Midline Vs Transverse incisions for hemi and segmental colectomies – a randomized controlled trial

A dissertation submitted to the Dr. M.G.R. Medical University, Tamil Nadu; in partial fulfillment of the requirement for the M.S. branch I (General Surgery) examination to be held in April 2013.

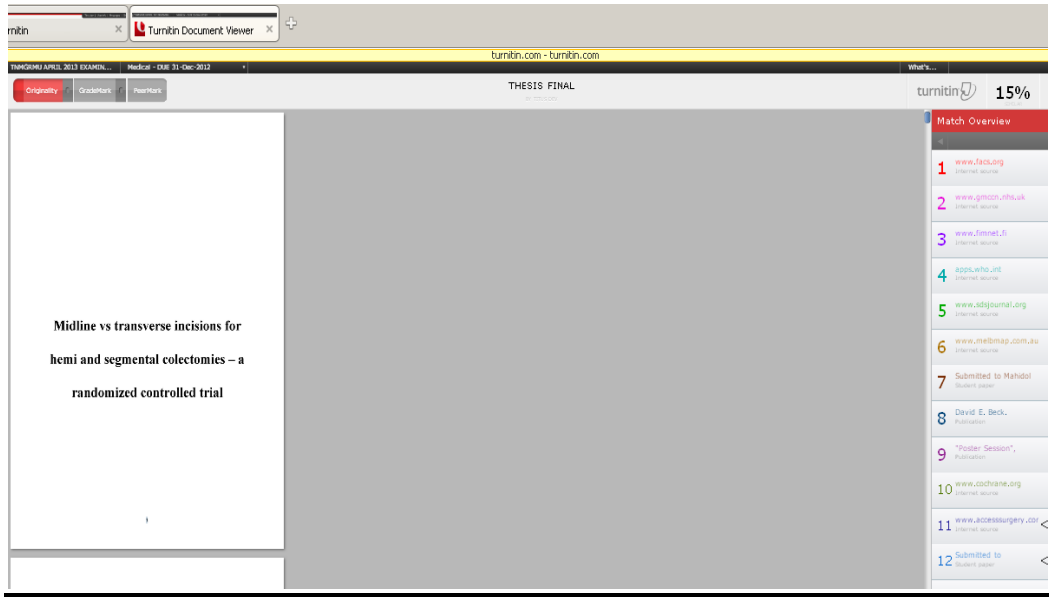
Certificate

This is to certify that the dissertation entitled *"Midline Vs Transverse incisions for hemi and segmental colectomies – a randomized controlled trial"* is a bonafide work done by Dr. Titus D.K., post graduate resident in Masters of General Surgery 2010-2013 at the Christian Medical College, Vellore, towards partial fulfillment for the MS General Surgery-Branch 1 final Examination to be held in April 2013.

Signature:

Guide:	**Head of the Department:**	**Principal:**
Dr. Benjamin Perakath Professor and Head, Dept of Surgery Unit 2, Christian Medical College, Vellore.	Dr. Benjamin Perakath Professor and Head, Dept of Surgery, Christian Medical College, Vellore.	Dr. Alfred Job Daniel Professor, Dept of Orthopedics, Christian Medical College Vellore.

Originality report



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ABSTRACT

TITLE OF THE ABSTRACT : Midline Vs transverse incisions for hemi and segmental colectomies – a randomized controlled trial

DEPARTMENT : General Surgery unit 2

NAME OF THE CANDIDATE : Titus D.K.

DEGREE AND SUBJECT : MS General Surgery

NAME OF THE GUIDE : Dr. Benjamin Perakath

OBJECTIVES:

To compare the effect of transverse and midline incisions for colectomies on:

- Duration of hospital stay
- Post operative pain
- Pulmonary function recovery
- Pulmonary infection
- Bowel function recovery
- Wound infection

METHODS:

A randomized double blinded controlled trial was carried out on 53 patients over 2 years, comparing midline and transverse incisions for hemi and segmental colectomies. Patients were randomized into midline or transverse incision groups. The mean difference in hospital stay was estimated with 95% confidence interval using two sample independent t test. Other outcomes were compared either using t-test or chi- square test, as appropriate. The difference was considered significant if p value was less than 0.05.

RESULTS:

Duration of hospital stay was shorter in the transverse group than the midline group with a p value of 0.016. Among secondary outcomes pain score was significantly less (p- 0.0001) in the transverse group (mean - 1.59) than the midline group (mean -2.62). Pulmonary function recovery and bowel function recovery were not significantly different. There was a trend for early recovery in both parameters in the transverse group. Length of incision is significantly (p-0.0003) less in the transverse group (mean 10.39 cm) than the midline group (mean- 12.04 cm).

Midline Vs transverse incisions for hemi and segmental colectomies – a randomized controlled trial

Introduction

Certain diseases of the colon necessitate excision of the whole or part of the colon; referred to as colectomy. In hemi or segmental colectomies only part of the colon is excised. Traditionally, hemicolectomies and segmental colectomies are done using a midline incision as they are easy to perform and can be extended if needed. However, studies have shown that midline incisions for abdominal surgery are associated with prolonged hospital stay, poor post operative recovery, higher rate of wound infection and incisional hernia. On the other hand, other studies have shown that transverse incisions for abdominal operations are associated with less post operative pain, better pulmonary function and earlier recovery. They have also shown that transverse incisions do not cause any difficulty in access during the operation (1).

Colectomies are done for benign or malignant conditions. The most common colonic condition which requires surgical intervention is colonic cancer. Colonic cancer is a disease with a major worldwide burden. It is the fourth most frequently diagnosed malignancy in both sexes with almost 1 million people developing colorectal cancer annually. It is the third most common cause of cancer death in the world, responsible for 630,000 deaths annually. In the United States, it is the third most common cancer in men and women, and the second most common cause of cancer death overall(2). In Asian countries the burden of colorectal cancers was less compare to developed countries. In India the incidence of colorectal cancer among men is 4.3 and women is 3.4 per 100,000 (3). Among colorectal cancers the rectum has the high incidence of malignancy (4).

Table 1: Relative incidence of colorectal cancers based on anatomical location

Site	Distribution (%)
Appendix	0.5
Caecum	12
Ascending colon	5
Hepatic flexure	2
Transverse colon	5.5
Splenic flexure	3
Descending colon	4
Sigmoid colon	21
Rectum	38
Anus	2

The main stay of treatment for colonic malignancy is surgical resection of the tumour. Surgery is based on the anatomic location of the tumour. The intent of surgery is to remove the primary tumour with adequate margin along with its regional lymphnodes. Lymphatic drainage of colon runs along its venous drainage so resection is based on its blood supply(5). The commonest operations performed on the colon are summarized in the table below(6).

Table 2: Common operations performed in colon

TUMOUR LOCATION	RESECTION	EXTENT	MAJOR BLOOD VESSEL
Caecum	Right hemicolectomy	Terminal ileum to mid transverse colon	Ileocolic, right colic , right branch of middle colic artery
Ascending colon	Right hemicolectomy	Terminal ileum to mid transverse colon	Ileocolic, right colic, right branch of middle colic artery
Hepatic flexure	Extended right hemicolectomy	Terminal ileum to splenic flexure	Ileocolic, right colic , middle colic artery
Transverse colon	Extended right hemicolectomy	Terminal ileum to splenic flexure	Ileocolic, right colic, middle colic artery
	Transverse colon resection	Transverse colon including both flexures	Middle colic artery
Splenic flexure	Extended left hemicolectomy	Right flexure to rectosigmoid junction	Middle colic, left colic, inferior mesenteric artery
Descending colon	Left hemicolectomy	Splenic flexure to recto sigmoid junction	Left branch of middle colic , inferior mesenteric artery
Sigmoid colon	Sigmoid colon resection	Descending colon to rectum	Inferior mesenteric , superior hemorrhoidal artery

Rarely, benign conditions which are not amenable to medical treatment may require surgical intervention, the commonest of which are tuberculosis and inflammatory bowel disease.

Whether the operation is done for benign or malignant conditions early recovery plays an important role in post operative outcome. There are several parameters which can influence post operative recovery. These factors can be pre operative, intra operative or post operative. Modifications of these factors for early recovery is known as Enhanced Recovery after Surgery(7). Few recommendations from enhanced recovery after surgery are(8)

Pre operative recommendations

1) Pre-operative counseling and training.

2) A curtailed fast (6 hours to solids and 2 hours to clear liquids) and pre-operative carbohydrate loading.

3) Avoidance of mechanical bowel preparation.

4) Deep vein thrombosis prophylaxis using low molecular weight heparin.

5) A single dose of prophylactic antibiotics covering both aerobic and anaerobic pathogens.

Per operative recommendations

1) High (80%) inspired oxygen concentration in the peri-operative period.

2) Prevention of hypothermia.

3) Goal directed intra-operative fluid therapy.

4) Preferable use of short and transverse incisions for open surgery.

5) Avoidance of post-operative drains and nasogastric tubes.

6) Short duration of epidural analgesia and local block

Post operative recommendations

1) Avoidance of opiates and the use of Paracetamol and non steroidal anti-inflammatory drugs (NSAIDS).

2) Early commencement of post-operative diet.

3) Early and structured post-operative mobilization.

4) Administration of restricted amounts of intravenous fluid.

5) Regular audit.

One of the per operative recommendations is transverse incision for laparotomy(8). Though transverse incisions are theoretically recommended in literature, there is no statistically significant evidence in literature to support the premise that transverse incisions are better for early recovery (9). For hemi and segmental colectomies, there are only 2 randomized controlled trials in literature which compare parameters like post operative pain, pulmonary function recovery, wound infection and hospital stay(10). However, no studies have shown a statistically significant difference in these parameters between midline and transverse incisions for colectomies. There are no randomized controlled trials comparing all types of colectomies. In this study we have compared midline and transverse incisions for right and left hemi colectomies and segmental (transverse or sigmoid) colectomies.

Aim

To compare the effect of transverse incisions with midline incisions on early post operative recovery among patients undergoing elective right / left hemicolectomy or segmental colectomy.

Objectives

To compare the effect of transverse and midline incisions in adults undergoing elective hemi or segmental colectomies on the following:

Primary objective:

- Duration of hospital stay

Secondary objectives:

- Post operative pain
- Pulmonary function recovery
- Pulmonary infection
- Bowel function recovery
- Wound infection

Literature review

A well planned incision is fundamental for any operation. A good abdominal incision is one that can be made relatively quickly, gives good exposure of intra-abdominal viscera, can easily be extended, is associated with few postoperative complications, and provides the greatest strength to the abdominal wall. Finally, a good cosmetic result should also be a goal(1).

Abdominal incisions for laparotomy can be divided into vertical and transverse incisions. Comparing both incisions, transverse incisions appear to have a better anatomical basis, based on the following features.

- Anatomical closure

Langer's lines of cleavage cross the skin of the anterior abdominal wall in a transverse direction. An incision parallel to these lines will therefore cause the least structural and cosmetic damage to the skin. The musculature of the anterior abdominal wall is composed of two groups, the "flat muscles" (the external oblique, the internal oblique, and the transverse) and the rectus muscles(1). The fascial fibres of the anterior abdominal wall lie in a transverse direction. In the midline, fibres join and form a relatively avascular linea alba. Fibres in the linea alba also run in transverse direction(11). A vertical incision therefore divides them, and suture closure of such vertical wounds places the suture material between the fibres. Contraction of the abdominal wall causes laterally-directed tension on the closure line and might cause the suture material to cut through by separation of the transversely orientated fibres. In contrast, a transverse incision opens the fascia along the fibres so that closure places the suture material around fascial fibres. On contraction, the fibres are approximated and the suture material causes minimal laterally-directed tension. Sectioning of one or both rectus muscle has no serious anatomical or physiological consequences. When healed, the muscles will have an extra tendinous intersection without functional impairment (1) .

- Blood supply

The blood supply to the abdominal wall is taken care of by two systems. Firstly, the inferior and superior epigastric arteries form a longitudinal anastomosis, which is called the deep epigastric arcade. The arcade is situated between the rectus abdominis muscle and its posterior sheath and supplies the muscle by perforating vessels. Some of these perforating vessels send small branches across the midline to supply the linea alba. Secondly, blood supply to the oblique and transverse muscles is taken care of by transverse segmental arteries that arise from the aorta and are situated between the internal oblique and transverse muscles. These segmental arteries follow a slightly downward transverse direction(11). Transection of the epigastric arteries has no physiological consequences for the blood supply to the abdominal wall, as the deep circumflex iliac artery and the lumbar and intercostal arteries also contribute to the anastomosis .

- Nerve supply

The innervation of the abdominal wall consists of ventral branches of the 5th to 12th thoracic nerves and the iliohypogastric and ilioinguinal nerves. They lie between the transverse muscle and the internal oblique muscle, where they form a free plexus. The ninth intercostal nerves pass transversely across the abdomen at a point one third the distance between the umbilicus and the xiphoid process. Nerves above this line tend to deviate upward, while those below deviate downwards. When an incision is made lateral to the midline, the transverse direction is least likely to cause injury to the nerves(1).

However, traditionally, abdominal operations for colectomies are performed through midline incisions. Six studies have compared midline and transverse incisions for elective right hemicolectomies(10,12–15), and one study for left hemicolectomy(16). Two of these studies

were randomized controlled trials. There is also a systematic review comparing midline and transverse incisions for all abdominal operations(9).

In literature, the first study comparing midline and transverse incisions was published in 2000 by Stipa. It was a non randomized study, 44 patients were included and 27 of them had midline incision and 17 had transverse incision. Pain, bowel function recovery, duration of hospital stay and complications were the outcomes assessed. Pain was less and bowel function recovery was faster in the transverse incision group but the difference was not statistically significant. Duration of hospital stay was assessed by how many patients were discharged on the 8^{th} post operative day. In midline group only 4% were discharged but in transverse group 47% were discharged by the 8^{th} day which was statistically significant (p value 0.001) (15).

In 2001, Lindregen and co workers published a randomized controlled trial comparing midline and transverse incisions for right colonic malignancy, with post operative pain and pulmonary function as major outcomes. In this study, out of 40 patients, 17 had transverse incisions and 23 had midline incisions. They concluded that transverse incision group had less post operative pain and early pulmonary function recovery(14).

Donati published a retrospective study in 2002 comparing midline and skin crease incisions for right hemicolectomy. It was a retrospective study, in which, out of 123 patients, 62 had a skin crease incision and 61 had a midline incision. It showed skin crease incision group had statistically significant quicker bowel function recovery, early fluid and solid intake and shorter hospital stay. They failed to show any difference in post operative complications, pain and narcotic requirements. They also showed a statistically significant decrease in length of skin incision and duration of operation in the skin crease incision group. (13).Brown has done a randomized controlled trial on 28 patients undergoing right hemicolectomy comparing midline and transverse incisions. Fourteen patients were randomized in each group. It was

concluded that there was no statistically significant difference in analgesic requirement, bowel function recovery and duration of hospital stay. There was a significant decrease in wound length in the transverse incision group (10).

Lohsiriwat from Thailand published a retrospective non randomized study in 2009. He compared 74 patients who underwent right hemicolectomy out of which 54 had midline incisions and 20 had transverse incisions. He found that transverse incisions had statistically significant reduction in analgesic requirement and hospital stay compared to the midline group. He did not find any significant difference in bowel function recovery and post operative complications(12).

Recently, in 2012 a retrospective study was published comparing midline and right Kochers' incision for right hemicolectomy. They found that duration of hospital stay was less in Kochers' incision group, but analgesic requirements, pulmonary compromise, bowel function recovery and post operative complications were the same in both groups (17).

A retrospective study by Kam was published in 2004. He compared 280 patients (140 midline incisions; 140 left skin crease incisions) who underwent elective, curative resection of left–sided colorectal cancers. Postoperative parameters for the skin crease incision group showed that feeding, ambulation, narcotic use and hospital stay were significantly better than the parameters in the midline group (16).

Most of these studies were retrospective and only 2 were prospective randomized controlled trials with the maximum sample size of 40. There are no systematic reviews comparing midline and transverse incision for colectomies.

However, the Cochrane database has a systematic review for all abdominal operations, comparing midline and transverse incisions. In this review there were 16 randomized controlled trials done for various abdominal operations including emergencies. Two randomized controlled trials done for right hemicolectomy were also included in this

systematic review. There were many confounding factors between the studies which made it difficult to analyze. All the studies did not have the same objectives and outcomes, and different methods were used in assessing the outcomes, so achieving a statistical significant outcome was difficult. However, results showed a trend towards transverse incision being better (9).Since most of these findings were not statistically significant, the authors concluded that analgesia use and pulmonary compromise may be reduced with a transverse/oblique incision but this does not seem to be significant clinically, as pulmonary complication rates and recovery times were the same. The wound dehiscence and rupture appears to be reduced with a transverse incision. The optimal incision for abdominal surgery still remains the preference of the surgeon (9).

There are no studies comparing all types of colectomies in the literature and the available randomized controlled trials for right hemi colectomies had small sample size. All studies are from developed countries, and there are no studies from the Indian population.

Our study is a properly structured randomized controlled trial in the Indian population comparing midline and transverse incision for hemi and segmental colectomies. Duration of hospital stay was taken as the primary outcome as this would represent early recovery from surgery. All the other parameters which could be influenced by the incision, and could potentially affect hospital stay were considered as secondary outcomes.

Methods

Type of study: Randomized controlled trial

Period of study: 2 years (September 2010 – August 2012)

Sample size calculation:

Sample size for this study was calculated based on a study by Lohsriwat which had hospital stay as primary out come and showed statistically significant less hospital stay in the transverse incision group(12).

Hospital stay

Mean +/- S.D in midline group = 7.9+/_ 3.2

Mean +/- S.D in transverse group = 6+/_2.5

Difference = 1.9 days

Power = 80%

Level of significance = 5%

$$\text{Formula(18)} \quad n = \frac{(Z1\text{-}\alpha/2 + Z1\text{-}\beta)^2 * 2\sigma^2}{d^2}$$

1. Alpha (α), typically 5% (sometimes written α =0.05) (19); also known as the false-positive rate.

2. Adequate power for a trial is widely accepted as 0.8 (or 80%). Power is defined as 1- β, where β, the false-negative rate, in this case would be 0.2 (or 20%).

3. Where the primary outcome is a continuous measurement such as blood pressure, an estimate of the natural variability in the population needed, usually the standard deviation, σ.

4. Where $z_{(1-\alpha/2)}$ and $z_{(1-\beta)}$ represent percentage points of the normal distribution for statistical significance level and power, respectively.

5. d represents the standardized difference (i.e. the treatment difference divided by its standard deviation) (18,19)**.**

Based on above values and formula, the calculated sample size is 36 in each arm.

Pre operative work up:

Pre operatively participants had contrast enhanced CT scan to assess the operability and metastatic state. Pre anesthesia check up was done for all to assess the ASA grade.

The ASA physical status classification system is a system for assessing the fitness of patients before surgery. In 1963 the American Society of Anesthesiologists (ASA) adopted the five-category physical status classification system; a sixth category was later added (20). These are:

1- A normal healthy patient.
2- A patient with mild systemic disease.
3- A patient with severe systemic disease.
4- A patient with severe systemic disease that is a constant threat to life.
5- A moribund patient who is not expected to survive without the operation.
6- A declared brain-dead patient whose organs are being removed for donor purposes.

Participants had a baseline spirometry and chest x-ray pre operatively. This was done so that pre operative values could be compared to post operative values, as a measure of pulmonary function (21). None of the participants had oral mechanical bowel preparation. However, for left hemicolectomies the participant had an enema on the day before surgery.

Participants:

All participants who were to undergo elective hemi or segmental colectomies under General Surgery Unit 2 and 4 in Christian Medical College hospital were included in this study, using following criteria:

.

a. **Inclusion criteria:**

- Elective operations for benign and malignant colonic disease
- No evidence of intra abdominal metastasis in malignant disease preoperatively as confirmed by CT scan.
- ASA grade 1-3(20)

b. **Exclusion criteria:**

- Emergency operations
- Palliative operations
- ASA grade > 3(20)
- Metastatic disease
    - Multiple liver metastasis
    - Gross ascites
    - Serosal and peritoneal deposits
- Patients planned for stoma pre operatively

All participants who fulfilled the inclusion criteria were given an information sheet in a language they could read and understand after which informed consent was taken. Participants who refused to give consent were excluded from the study and had traditional midline incision.

Randomization:

Patients were randomized into midline group and transverse group.

Block randomization codes were generated using a computer program (raloc)(22).

Concealment:

Opaque, sealed, unmarked, sequential envelopes opened just before operation were used for allocation concealment (23).

Blinding and masking:

This was a double blinded study in which the participant and the outcome assessor were blinded (24).

Specific protocols were followed for all participants regarding analgesia, antibiotics and dressings as outlined below.

Intra operatively all participants received epidural analgesia adequately covering the incisions. The level of epidural catheter placement was left to the anaesthetist. A premixed solution of Inj. Fentanyl and Inj. Bupivacaine was used for infusion(25). The participant received a single dose of Inj. Cefazolin 1 gm, Inj. Flagyl 500mg and Inj. Gentamicin 160mg or Inj. Ciprofloxacin 200mg depending upon renal status just before skin incision.

The sealed envelope was opened and type of incision was read out to the surgeon. The operation was performed in the usual manner. Post operatively, a vertical as well as transverse dressing was placed on the operating table. This was done to blind the pain score assessor regarding type of incision. Pain score was assessed by a nurse twice daily using a visual analogue scale and documented.

Post - operatively the participant was given oxygen at 6litres/ min for 6 hours. No post operative antibiotics were administered. Chest physiotherapy, steam inhalation and incentive spirometry were given to all participants throughout their hospital stay.

Analgesia protocol:

Epidural analgesia was removed after 72 hours. Change in epidural dose or early removal of epidural was documented in the epidural chart. Inj/Tab. diclofenac 50 mg q8h or Inj/Tab. Tramadol 50mg q8h were used for post epidural analgesia, depending on renal function. While on the epidural infusion, Inj diclofenac 50mg or Inj Tramadol 50 mg were used for breakthrough analgesia. After epidural removal Inj. Morphine 0.1mg/kg subcutaneously was used for breakthrough analgesia. The participant also received Inj Paracetamol 1 gram six hourly while in hospital post operatively. If any other mode of analgesia was used, the reason was documented clearly.

Primary outcome:

Duration of hospital stay:

Transverse incisions are thought to result in less post operative pain and less pulmonary complications, resulting in early ambulation and discharge. Therefore hospital stay was used

as primary outcome. However, to avoid co morbid conditions and other factors which could influence the duration of hospital stay, duration of hospital stay was calculated from the day of operation to the day the patient was deemed fit enough to be discharged. Fitness was decided by the surgical team using these criteria:

- Afebrile for 24 hrs
- Taking normal diet
- Passed stools and flatus post operatively
- No intra venous fluid

If hospital stay was prolonged due to co morbid conditions that was mentioned separately. Re- admission or reoperation was also noted.

Secondary outcomes:

- **Post operative pain**

This was assessed by documenting the pain score using visual analog scale twice daily during the hospital stay. The dose of epidural required for analgesia was calculated and whether breakthrough analgesia was required or not assessed and if required, the number of doses noted. We also documented the mode of analgesia used after removal of the epidural catheter. The above mentioned guidelines for analgesic use were followed for all participants.

- **Pulmonary function recovery**

Pulmonary function status was assessed by spirometry. One baseline spirometry was done preoperatively in the pulmonary function lab. Post operatively this was repeated twice, one at 24 hours and one at 72 hours. Forced Vital Capacity (FVC), Forced Expiratory Volume in 1 minute (FEV1)

and FEV1 and FVC ratio were measured for both groups using a portable spirometer (21).

- **Pulmonary infection**

Pulmonary infection was diagnosed by using modified CDC criteria for nosocomial pneumonia(26,27).

Acute nosocomial pneumonia is broadly defined as pneumonia characterized by a new and persistent infiltrate (radiographically present for greater than 48 hours) PLUS

Two of the following:

* Core temperature > 38.3°C

* Blood leukocytes > 10,000 cells/mL

* Purulent tracheal secretions

Total white cell counts were checked at 72 hours. The patient was assessed for purulent tracheal secretion and rise in temperature. If 2 out of 3 of these criteria were present, participant was subjected to a chest x ray and, if positive findings suggestive of pulmonary infection were present, the chest x- ray was repeated after 48 hours. If the criteria were fulfilled, the participant was diagnosed to have pulmonary infection

- **Bowel motility recovery**

This was assessed by time taken to pass flatus and faeces post operatively, calculated in hours from the end of operation.

- **Wound infection**

This was diagnosed using CDC criteria for surgical site infection (28).

WOUND INFECTION DIAGNOSTIC CRITERIA

Surgical site infection (SSI)

Superficial incisional SSI

Infection occurs within 30 days after the operation *and* infection involves only skin or subcutaneous tissue of the incision *and* at least *one* of the following:

1. Purulent drainage, with or without laboratory confirmation.

2. Organisms isolated from an aseptically obtained culture of fluid or tissue.

3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat. Superficial incision deliberately opened by surgeon, unless incision is culture-negative.

4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Deep incisional SSI

Infection occurs within 30 days after the operation, infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision *and* at least *one* of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.

2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38° C), localized pain, or tenderness, unless site is culture-negative.

3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.

2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

Wound infection was diagnosed based on these criteria by the surgical team every day.

Other parameters which were compared:

- **Length of incision**

Measured in centimeters at the end of surgery by the operating surgeon or first assistant and documented

- **Duration of surgery in minutes**

Calculated from skin incision to closing of skin written by the operating surgeon or first assistant at the end of surgery

- Resected pathology specimens were assessed for
    - Nodal status
    - Margin status
    - TNM staging if malignant(29)

These parameters were assessed to study the difficulty and accessibility while using these incisions.

- **Rate of readmission**
    - Reason and post operative day were noted
- **Rate of re exploration**
    - Reason and post operative day were noted

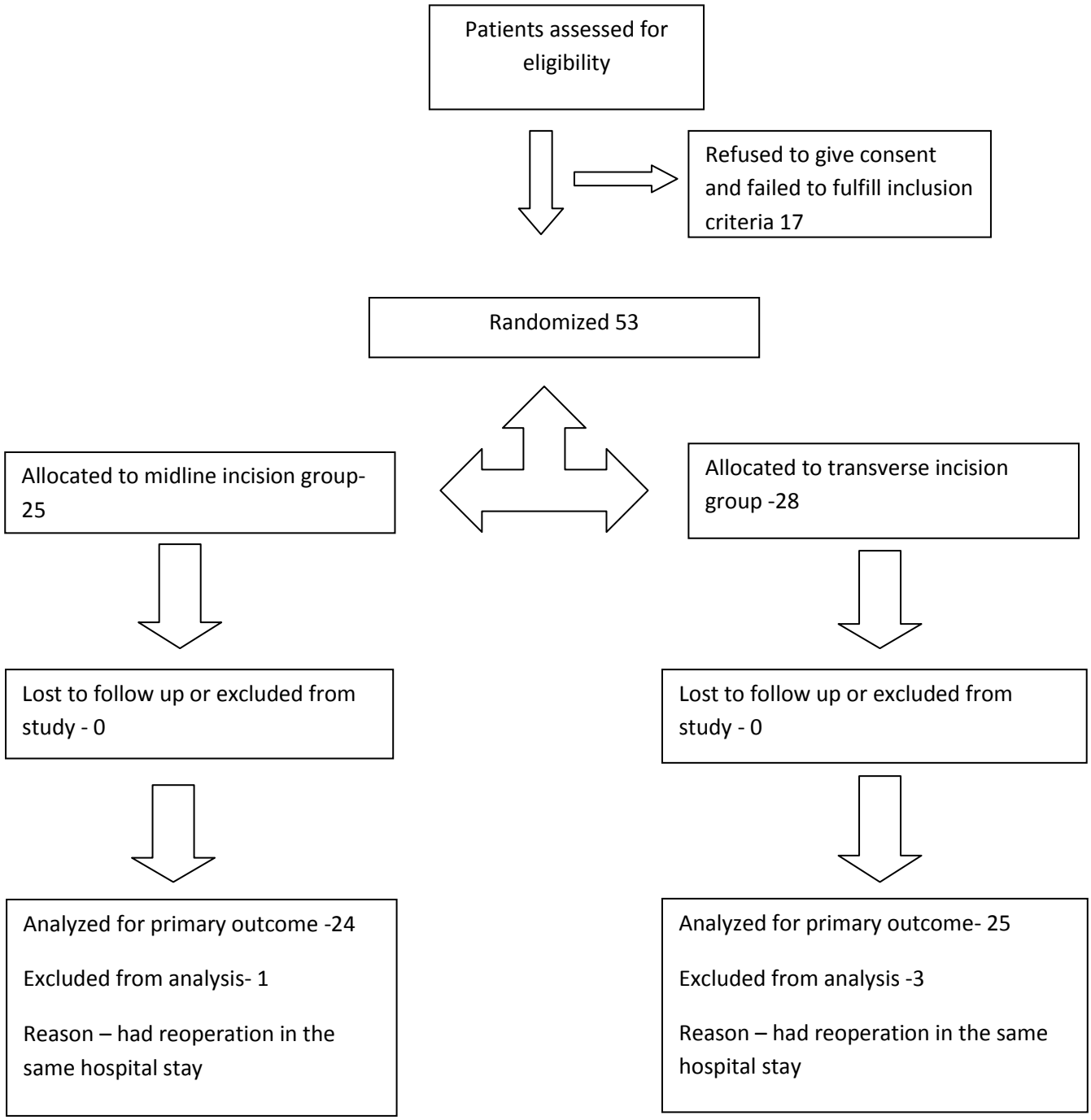
These factors were assessed to compare immediate operative complications in both groups.

Statistical analysis:

The primary outcome variable for this study was the duration of hospital stay. The mean duration between the two study groups were compared using two-sample independent - t- test. The mean difference in hospital stay was estimated with 95% confidence interval. The secondary outcome variables were compared between the two groups either using t-test or chi- square test, as appropriate. The difference was considered significant if p value was less than 0.05(24).

Results

Participants' flow chart



Recruitment

All patients who underwent hemi or segmental colectomies for benign or malignant conditions under General Surgery unit 2 and 4 in Christian Medical College Hospital Vellore, Tamil Nadu, India from 26/08/2010 to 25/08/2012 for a period of 2 years were included in the study after taking informed consent. The study was stopped before completing the sample size as the dissertation had to be submitted as part of MS General Surgery Course.

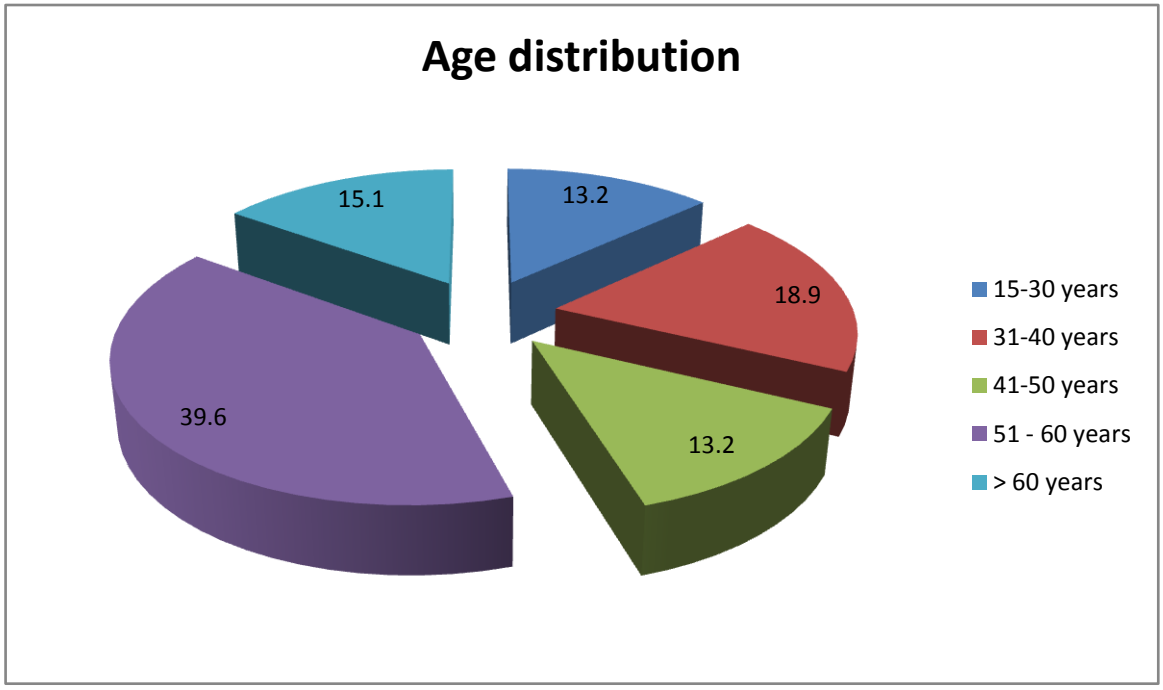
Base line data

The calculated sample size was 72, 36 in each arm. We could recruit only 53 participants in the given time frame. The midline incision arm had 25 participants and the transverse incision arm had 28 participants.

Age distribution:

Among 53 participants 40% of them were in the age group of 41-50 years. Age distribution of the study group is given below.

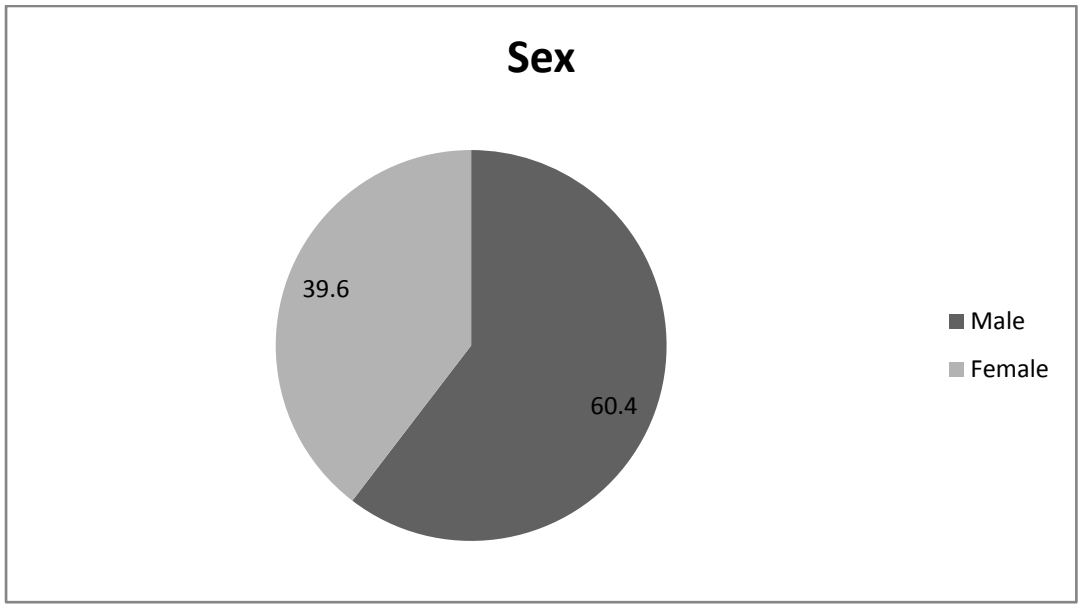
Fig1: Pie chart showing percentage distribution of patients according to age group.



Sex distribution

Sixty percent of the study group was male.

Fig.2: Pie chart showing percentage distribution of patients according to sex.



Body Mass Index (BMI)

Participants were classified into different groups according to their body weight(30,31)

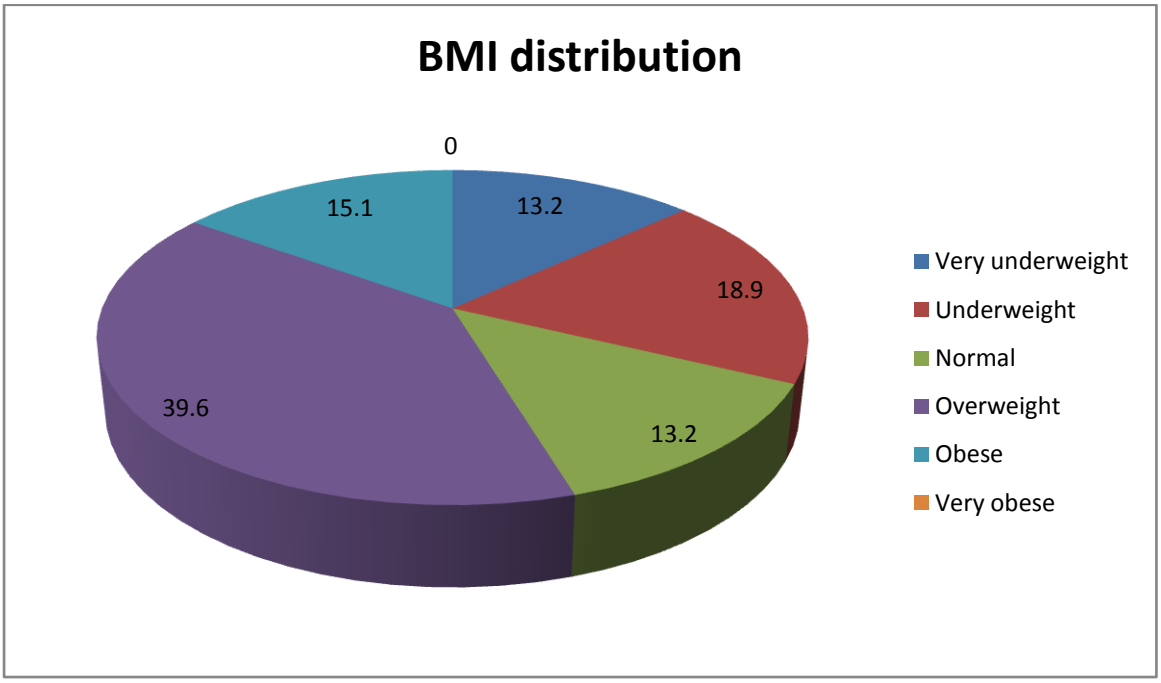
Table 3: BMI classification

BMI value	Category
</= 15	Very underweight
16-18.4	Underweight
18.5-24.9	Normal
25-29.9	Overweight
30-34.9	Obese
>/=35	Very obese

BMI Distribution

Forty percent of the study group fell in the overweight category. There was no one in the very obese category.

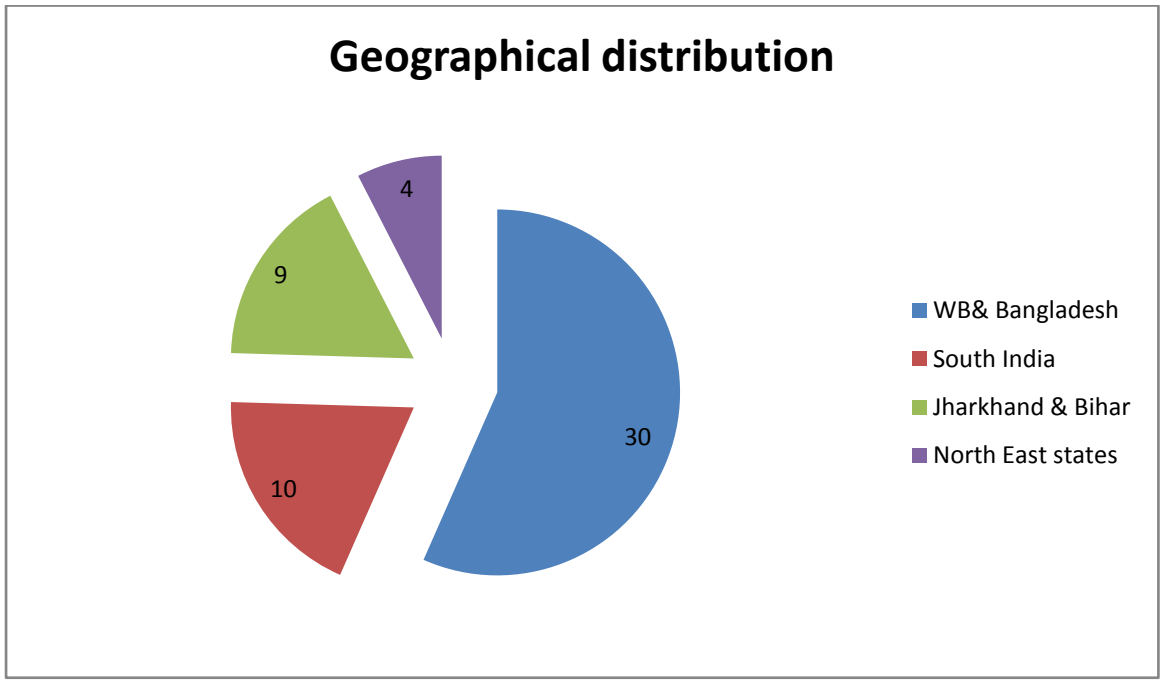
Fig.3: Pie chart showing percentage distribution of patients according to BMI



Geographical distribution

In the study group out of 53, 29 participants were from West Bengal and Bangladesh, 10 from South India, 9 from Jharkhand and Bihar and 4 from North East states.

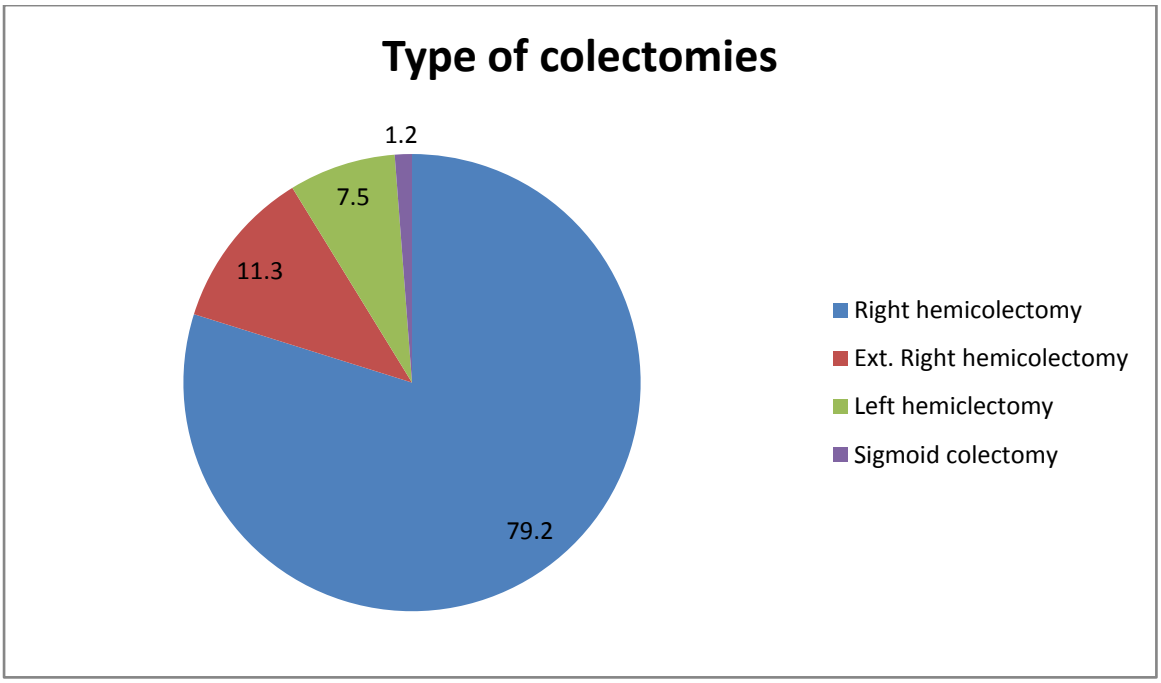
Fig.4: Pie chart showing distribution of patients (number) based on geography.



Type of colectomies

Among 53 participants, 42 participants underwent right hemicolectomy, 6 participants underwent extended right hemicolectomy, 4 participants had left hemicolectomies and one participant had sigmoid colectomy.

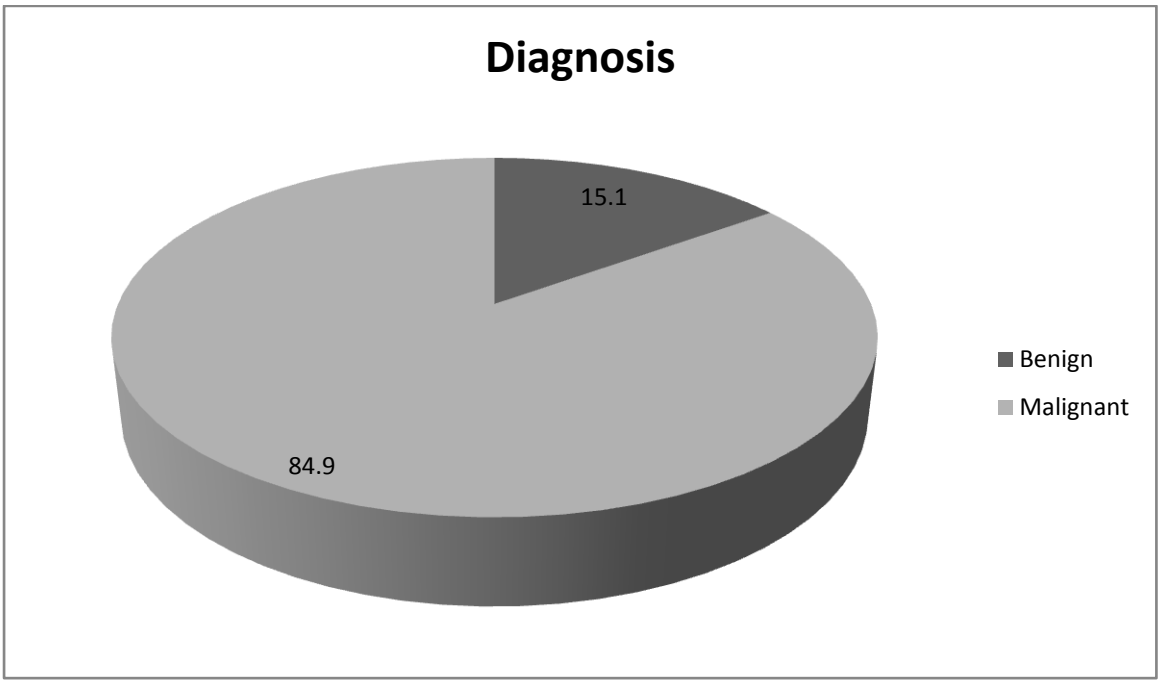
Fig.:5 Pie chart showing percentage of patients according to type of colectomies



Diagnosis:

Among 53 participants 45 participants had malignant disease and 8 had benign pathology

Fig.6: Pie chart showing benign and malignant cases in the study group



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Demographic profile

Demographic profile was compared between both groups and summarized below

Table4: Demographic profile summary

Demographic profile	value	Midline incision group	Transverse incision group	p value
Age	Mean(95% C.I)	47 (40.69 - 53.30)	49.75(45.08 - 54.41)	**0.47**
Sex male	No (%)	17(68)	15(53.57)	**0.28**
Sex female	No (%)	8(32)	13(46.43)	
BMI	Mean(95% C.I)	21.85(20.04 - 23.66)	21.87(20.65 23.08)	**0.99**

Co-morbidities

Conditions which can affect any of the primary or secondary outcomes have been assessed in co morbidities. Assessment of pulmonary function and pulmonary infection can be affected by diseases like asthma, COPD or any other lung diseases (32–34). Diseases like diabetes mellitus, previous history of chemotherapy or radiotherapy will affect the wound healing process and they may be prone for surgical site infection (35,36). Duration of hospital stay and wound infection rate can be affected by these diseases. Previous abdominal surgery can cause intra abdominal adhesions and prolong the duration of surgery (37). These parameters were compared between both groups and summarized below.

Table5: Co morbidities - summary

Parameters	Midline incision		Transverse incision		p - Value
	n	%	n	%	
Asthma					
Yes	-	-	-	-	1.000
No	25	100.0	28	100.0	
COPD					
Yes	2	8.00	1	3.57	0.486
No	23	92.00	27	96.43	
Diabetes					
Yes	3	12.00	5	17.86	0.35
No	22	88.00	23	82.14	
Pre op Chemo					
Yes	-	-	1	3.57	0.340
No	25	100.0	27	96.43	
Pre op RT					
Yes	-	-	1	3.57	0.340
No	25	100.0	27	96.43	
Previous abdominal surgery					
Yes	8	32.00	12	42.86	0.416
No	17	68.00	16	57.14	

Duration of operation

Some authors feel that transverse incision does not give good access to the tumour. In this study duration of operation was compared between both the groups to see whether the transverse incision group took longer to complete the operation. The mean time for midline and transverse group was 145.8 minutes and 135.53 minutes respectively. The duration of operation was shorter in the transverse incision group. The difference was not statistically significant**.**

Duration of operation

Table 6: Comparison of duration of operation between the midline and the transverse group

Group	N	Mean (hrs)	S.D.	Minimum	Maximum	p - Value
Midline incision	25	145.8	34.51	90	240	**0.24**
Transverse incision	28	135.53	28.52	90	195	

Length of incision

The length of incision was measured between both groups and compared. Mean length of incision in transverse group was 10.39 cm. In midline group it was 12.04 cm and this difference was statistically significant (**p-0.0003**).

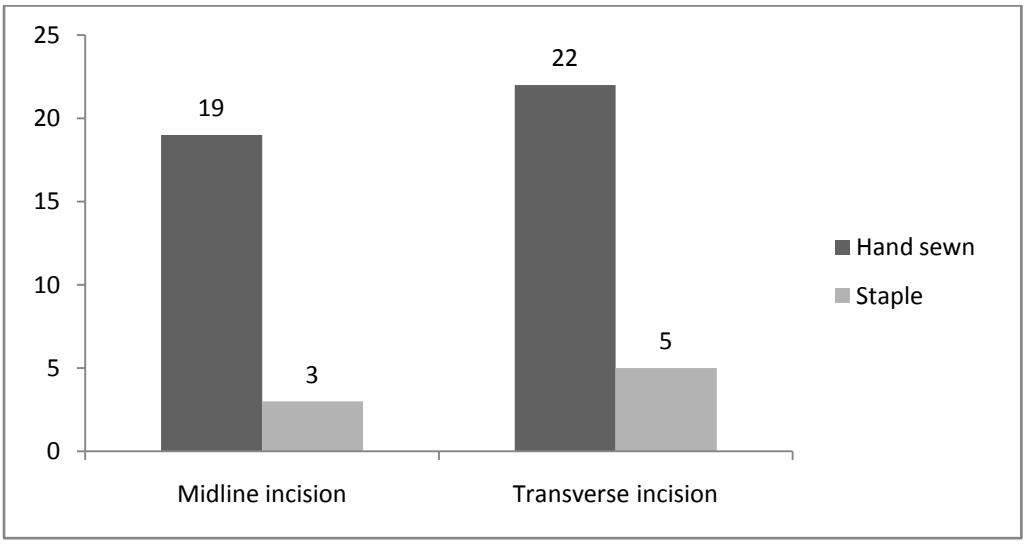
Table 7: Comparison of length of incision between the midline and the transverse group

Group	N	Mean (cms)	S.D.	Minimum	Maximum	p - Value
Midline incision	25	12.04	2.19	9	20	**0.0003**
Transverse incision	28	10.39	2.02	8	18	

Type of anastomosis:

For joining the ends of the bowel sutures or staples were used. In the midline group out of 25 participants only 22 had anastomosis. Nineteen of them had hand sewn anastomosis and three had a stapled anastomosis. In the transverse incision group, out of 28, 27 had anastomosis and 5 of them had a stapled anastomosis, the other 22 had hand sewn anastomosis. This was compared between both groups and the difference was not statistically significant.

Fig.7: Bar diagram showing type of anastomosis in both the groups

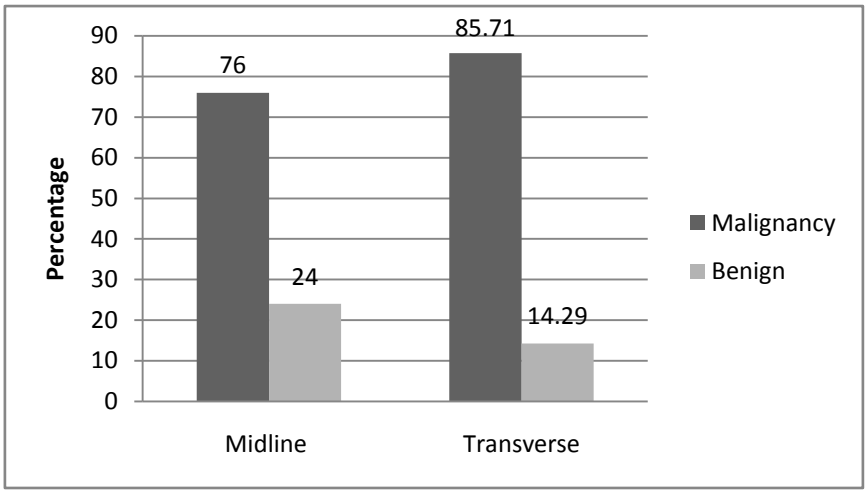


p value 0.646

Diagnosis

Benign and malignant diseases were compared between both the groups. The midline group had 19 malignant conditions and 6 benign conditions. The transverse group on the other hand had 24 malignant conditions and only 4 benign conditions. This difference was not statistically significant (**p value -0.367**).

Fig.8: Bar diagram showing percentage distribution of benign and malignant condition in both the groups

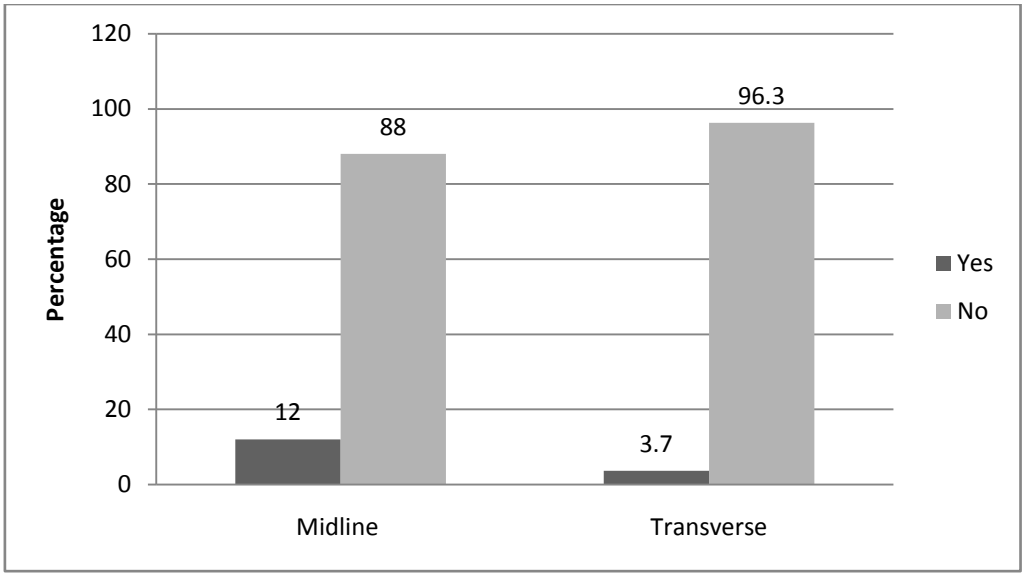


p- 0.36

Stoma creation

All patients who were planned for stoma pre operatively were excluded from this study. However participants who were planned for primary anastomosis but had to have a stoma because of various reasons were included. In the transverse incision group, only 1 person had stoma, but in midline group 3 participants had a stoma; this difference was not statistically significant (P value – 0.638).

Fig.9: Bar diagram showing number of patients who had stoma creation in both the groups.



p- 0.63

Table 8: Summary of intra operative parameters

Parameter	Value measured	Midline incision group	Transverse incision group	p value
Benign	**No (%)**	**6 (24)**	**4 (14.29)**	**0.367**
Malignant	**No (%)**	**19 (76)**	**24 (85.71)**	
Length of incision	**Mean (p25-p75)**	**12.04 (9, 20)**	**10.39 (8, 18)**	***0.0003***
Hand sewn anastomosis	**No (%)**	**19 (86.4)**	**22 (81.5)**	**0.646**
Staple anastomosis	**No (%)**	**3 (13.6)**	**5 (18.5)**	
Stoma	**No (%)**	**3 (12)**	**1 (3.7)**	**0.638**
Duration of operation	**Mean (min, max)**	**145.8 (90, 240)**	**135.53 (90, 195)**	**0.24**

Oncological Assessment

Number of nodes

The oncological stage and resection status were compared in those who had malignant disease.

The total number of nodes resected was compared between both groups, the midline group had a mean value of 16.78 nodes and transverse group had a mean value of 15.83 and the difference was not significant.

Table 9: Comparison of Number of nodes harvested between the midline and the transverse incision group

Group	n	Mean (n)	S.D.	Minimum	Maximum	p – Value
Midline incision	18	16.78	7.63	8	38	**0.87**
Transverse incision	24	15.83	6.44	6	37	

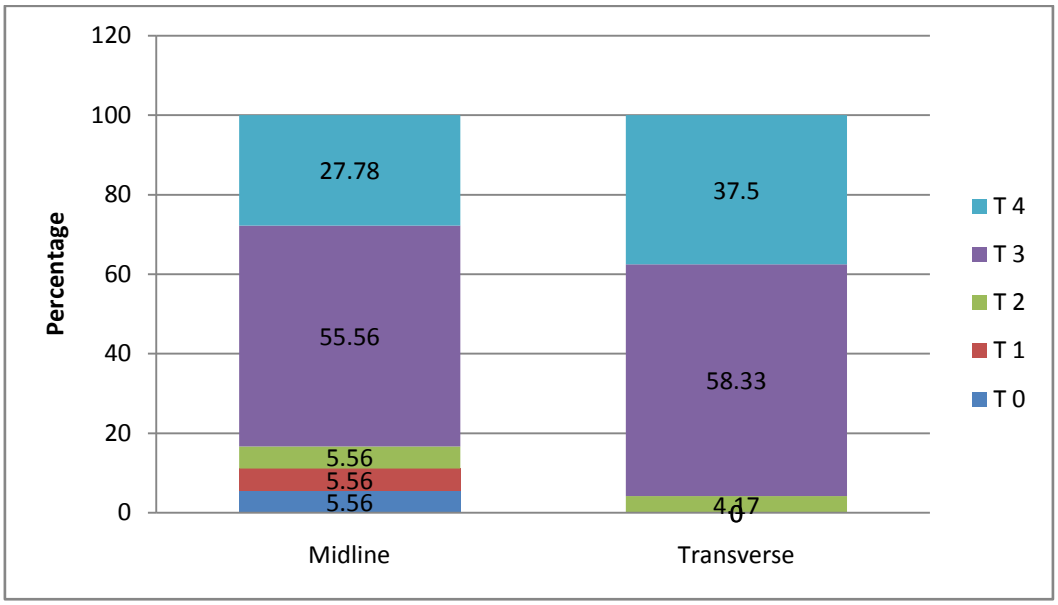
TNM stage

Malignant tumours were compared for their TNM staging (29) and the difference was not statistically significant.

T – Tumor size

In both groups most tumours were T3 or T4 tumours. In the midline group, 10 participants were T3 and 5 were T4. In the transverse incision group 14 participants were T3 and 9 T4. This difference was not significant (p = 0.556).

Fig.10: Bar diagram comparing tumour size in both the groups

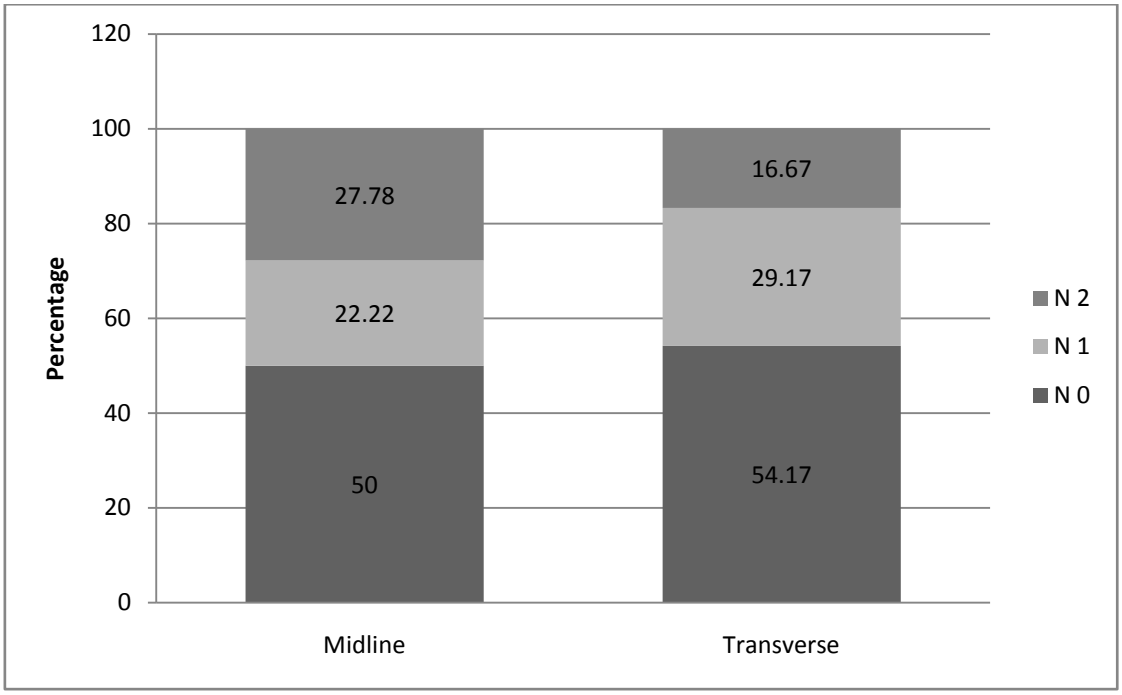


p value 0.556

N – Nodal status

In the midline group, out of 18 participants, 9 were N0, 4 were N1 and 5 were N2. In the transverse group, out of 24 participants, 13 were N0, 7 were N1 and 4 were N2.

Fig.11 Bar diagram comparing nodal status between both the groups

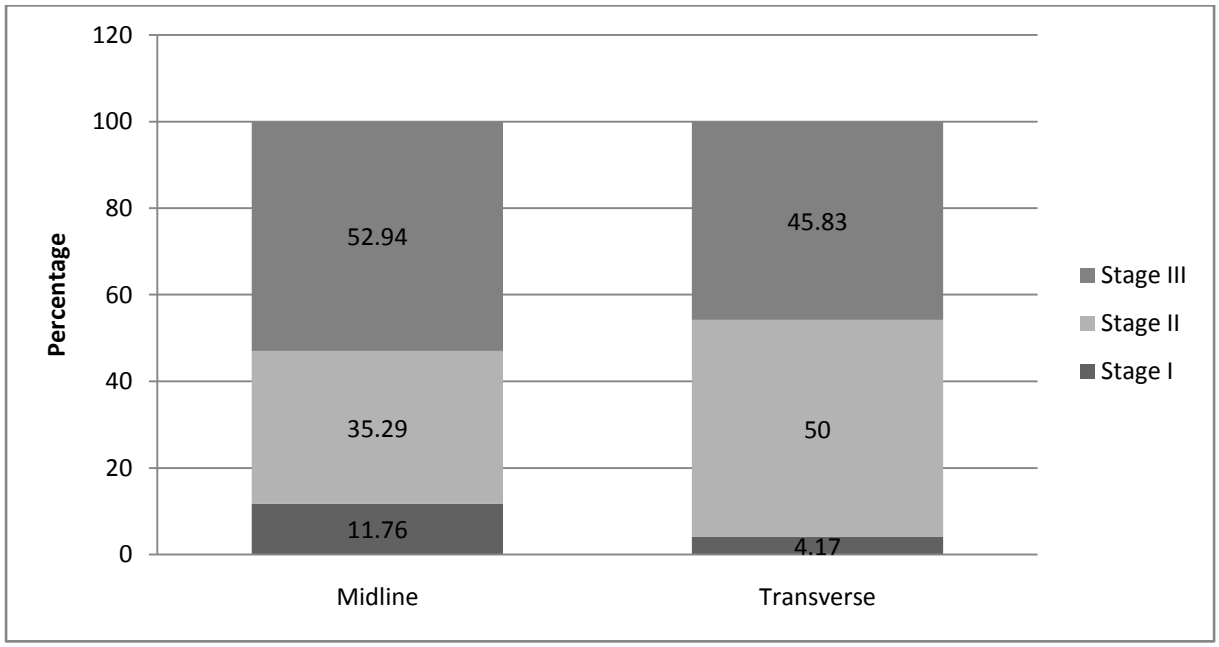


p value 0.665

Stage

The midline incision group had 50% stage II disease and transverse incision group had 52% stage III disease. However this difference was not statistically significant (**p = 0.50**).

Fig.12: Percentage distribution of patients among the different stages in the midline and the transverse incision group.



p value 0.5

Table 10: Summary of oncological resection comparison

Parameter		Value measured	Midline incision group	Transverse incision group	p value
Positive proximal margin		No (%)	0 (0)	0 (0)	
Positive distal margin		No (%)	0 (0)	0 (0)	
No of nodes resected		Mean (p25-p75)	16.78 (8, 38)	15.83 (6, 37)	0.87
T stage	Tis	No (%)	1 (5.56)	0(0)	0.556
	T1	No (%)	1 (5.56)	0(0)	
	T2	No (%)	1 (5.56)	1 (4.17)	
	T3	No (%)	10 (55.56)	14 (58.33)	
	T4	No (%)	5 (27.28)	9 (37.50)	
N stage	N0	No (%)	9 (50)	13 (54.17)	0.665
	N1	No (%)	4 (22.22)	7 (29.17)	
	N2	No (%)	5 (27.28)	4 (16.67)	
TNM stage	I	No (%)	2 (11.76)	1 (4.17)	0.502
	II	No (%)	6 (35.29)	12 (50)	
	III	No (%)	9 (52.94)	11 (45.83)	

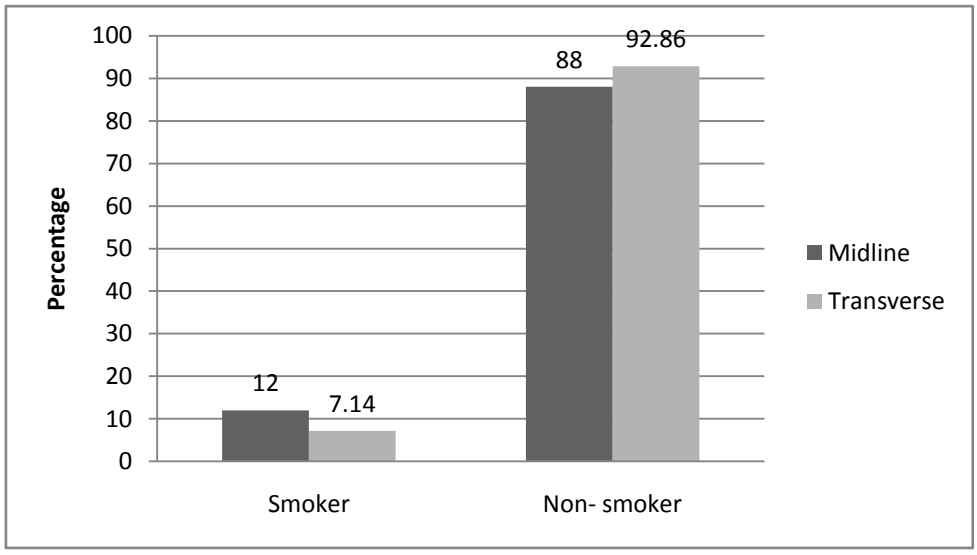
History of smoking

Pulmonary function recovery and pulmonary infection have been assessed as secondary outcomes in this study. Pulmonary function recovery was assessed using spirometry. Present or past history of smoking can affect the values of pulmonary function tests(38,39). However in this study difference in their distribution between both groups were statistically insignificant.

Smoking Status

In midline group there were 3 smokers and transverse group had 2 smokers

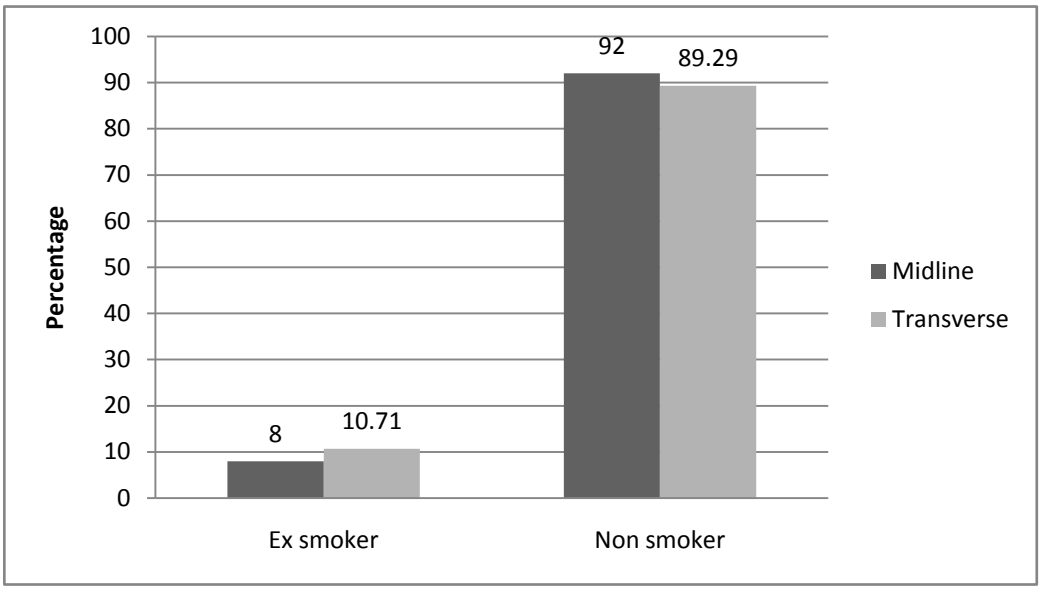
Fig13: Bar diagram comparing percentage of smokers and non smokers in both the groups



Ex smokers

There were two and three ex smokers in midline and transverse group respectively.

Fig.14: Bar diagram comparing ex smokers and non smokers in both the groups



p- 0.736

Outcomes

Duration of Hospital Stay

Duration of hospital stay was calculated from the day of operation to the day when the patient was declared fit for discharge. However if patients underwent re operation during the same hospital stay, they were excluded from the calculation. After exclusion, the midline incision group had 24 participants and transverse incision group had 25 participants. To compare both groups we took quantiles into account. P50 OR Q2 otherwise known as median is the 50^{th} percentile. P50 was taken into consideration to avoid extreme values affecting the results. P25 is 25^{th} percentile and p75 is 75^{th} percentile. P50 means 50% of values will be less than p50 value. P50duration of hospital stay in midline and transverse incision group was 6 and 5 respectively and the difference was statistically significant.

Table 11: Comparison of duration of hospital stay between the midline and the transverse group

Group	**n**	**P50 (days)**	**P25**	**P75**	**S.D.**	**p - Value**
Midline incision	24	6	**5**	**6**	1.10	**0.0162**
Transverse incision	25	5	4	6	3.50	

Pain

Pain was assessed using the visual analogue scale. Pain score was measured twice daily and the average was calculated for each day. Overall average of pain score for the patient was taken for calculation. The mean value in the midline group was 2.62. The transverse group had a mean value of 1.59. P value was 0.0001 which was statistically significant.

Other factors that could influence the pain score were also assessed. Epidural was given to most patients and the day of epidural removal was noted. The day epidural was removed was assessed between the midline and the transverse group. There was no statistically significant difference in the day of epidural removal.

The level of epidural catheter placement was also assessed. There was no statistically significant difference between the levels of placement. The most common level the catheter was placed was T 10 in both groups.

The dose of epidural was calculated everyday for all 3 days and the average dose was taken and compared. Mean value in the midline group was 5.04 and transverse group was 4.7. The p value of this was 0.16 which was not significant.

Post epidural analgesia usage were assessed for each day between both groups and compared, and the difference was insignificant.

Pain score

Table12: Comparison of pain score between the midline and the transverse group

Group	n	Mean	S.D.	Minimum	Maximum	p - Value
Midline incision	25	2.62	0.76	1.2	4	**0.0001**
Transverse incision	28	1.59	0.52	0.6	2.6	

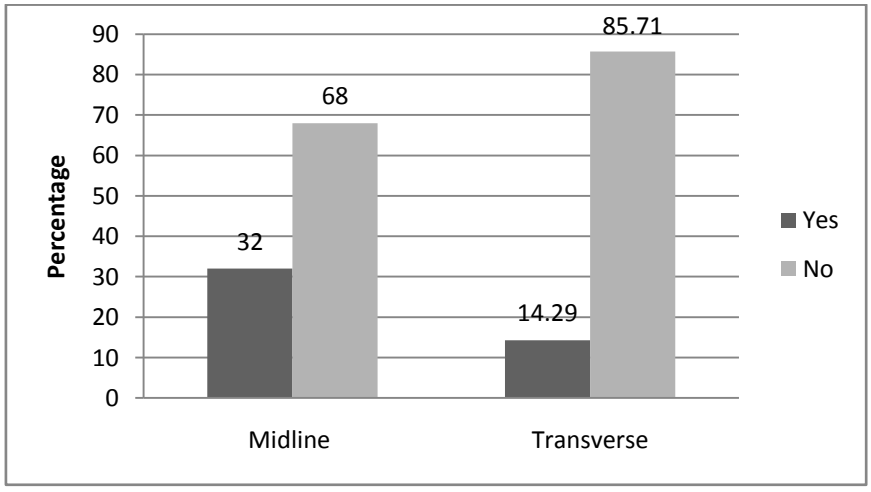
Epidural dose average

Table13: Comparison of average epidural dose between the midline and the transverse group

Group	n	Mean	S.D.	Minimum	Maximum	p - Value
Midline incision	25	5.04	1.07	3.1	7.6	**0.16**
Transverse incision	26	4.70	0.56	3.4	5.9	

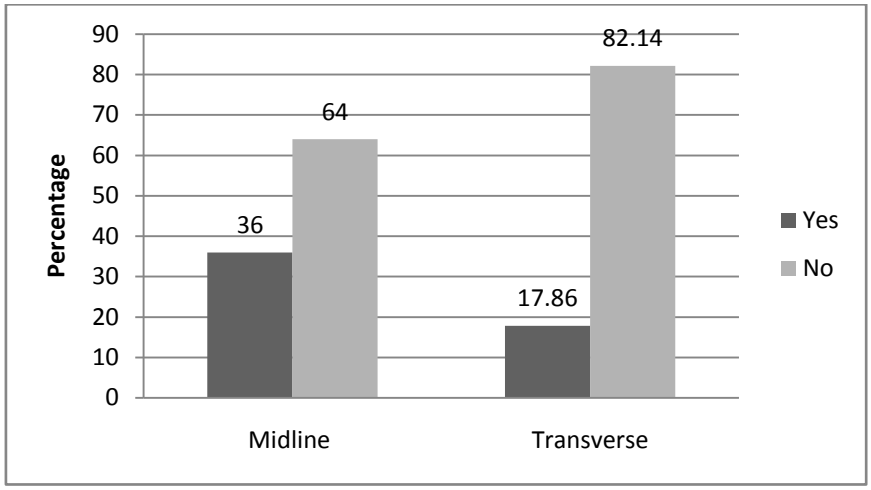
Break through analgesia (BTA) required was calculated for each day and p value was calculated. There was no statistically significant difference between both groups in usage of break through analgesia.

Fig.15: Bar diagram comparing BTA on day1 between the midline and the transverse group



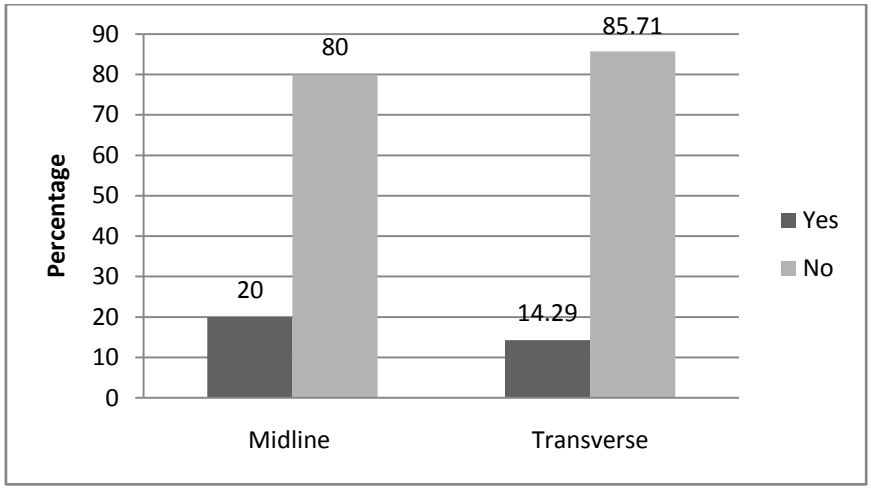
p value – 0.124

Fig.16: Bar diagram comparing BTA on day2 between the midline and the transverse group



p value -0.135

Fig.17: Bar diagram comparing BTA on day3 between the midline and the transverse group



p value -0.58

Epidural catheter removal

The epidural catheter was usually removed 72 hours post operatively. However, due to various reasons like non functioning epidural or hypotension, some epidurals were removed early. These parameters were also compared and there was no significant difference was found between the groups.

Table 14: Comparison of day of epidural removal between the midline and the transverse group

Variables	Midline incision		Transverse incision		p - Value
	n	%	n	%	
Epidural removed					
Day1	5	20.0	1	3.85	
Day2	1	4.00	-	-	**0.110**
Day3	-	-	2	7.69	
Day4	19	76.00	23	88.46	

Post epidural analgesia

Morphine, Diclofenac or Tramadol were used for analgesia after removal of the epidural. The number of doses was compared in both groups for each day. There was no statistical difference between both groups.

Table 15: Comparison of post epidural analgesia usage between the midline and the transverse group

Post epidural analgesia day	No of patients received post epidural analgesia		p value
	Midline	Transverse	
1	6	5	0.649
2	7	4	1
3	7	6	0.28
4	25	28	0.43
5	21	26	1.00
6	11	13	0.42

Among all the parameters compared regarding post operative pain, only pain score showed statistically significant difference between both groups (p value 0.0001). The transverse group had less pain compared to the midline group.

Pulmonary function

Pulmonary function was assessed using spirometry. Three values were calculated, Forced Vital Capacity, Forced Expiratory Volume at 1 minute and their ratio (FEV1/FVC). Midline or transverse incision will affect pulmonary function assessment by impairing diaphragmatic movement which results in restrictive pattern of lung pathology. FVC is a better representative of restrictive lung conditions(21,34). Differences in all 3 values were calculated between pre op and 24 hours value, pre op and 72 hours value and 72 and 24 hours value. These differences were compared between both groups. Out of all three parameters FVC between pre operative value and 24 hours was just significant (p value 0.05). The midline group had a mean value of 1.1, the transverse group had a mean value of only 0.75.

FEV1

Table 16: Comparison of FEV1 between the midline and the transverse group

Group	n	Mean	S.D.	95% confidence interval		p - Value
Pre op – 24hrs						
Midline incision	20	0.962	0.09	0.76	1.15	**0.103**
Transverse	21	0.698	0.12	0.43	0.95	
Pre op – 72hrs						
Midline incision	19	1.06	0.49	0.82	1.30	**0.37**
Transverse	21	0.91	0.53	0.67	1.15	
72 hrs – 24 hrs						
Midline incision	18	0.10	0.44	-0.11	0.31	**0.71**
Transverse	20	0.15	0.47	-0.06	0.37	

FVC

Table 17: Comparison of FVC between the midline and the transverse group

Group	n	Mean	S.D.	95% confidence interval		p - Value
Pre op – 24hrs						
Midline incision	20	1.10	0.50	0.86	1.33	**0.05**
Transverse	21	0.75	0.59	0.48	1.02	
Pre op – 72hrs						
Midline incision	19	1.25	0.11	1.00	1.50	**0.08**
Transverse	21	0.93	0.13	0.64	1.21	
72 hrs – 24 hrs						
Midline incision	18	0.13	0.48	-0.109	0.37	**0.88**
Transverse	20	0.109	0.54	-0.144	0.36	

FEV1/FVC

Table 18: Comparison of FEV1/FVC between the midline and the transverse group

Group	n	Mean	S.D.	95% confidence interval		p - Value
Pre op – 24hrs						
Midline incision	20	2.58	9.2	-1.87	7.04	**0.70**
Transverse	21	3.70	9.17	-0.47	7.88	
Pre op – 72hrs						
Midline incision	19	2.67	8.8	-2.01	5.09	**0.86**
Transverse	21	3.7	8.2	-0..22	5.69	
72 hrs – 24 hrs						
Midline incision	18	1.1	9.00	-3.36	5.57	**0.17**
Transverse	20	-3.27	10.36	-8.12	1.57	

Pulmonary Infection

There was one case each of proven pulmonary infection in both groups which was not statistically significant (**p = 0.935**)

Fig18: Bar diagram comparing percentage of pulmonary infection between the midline and the transverse group

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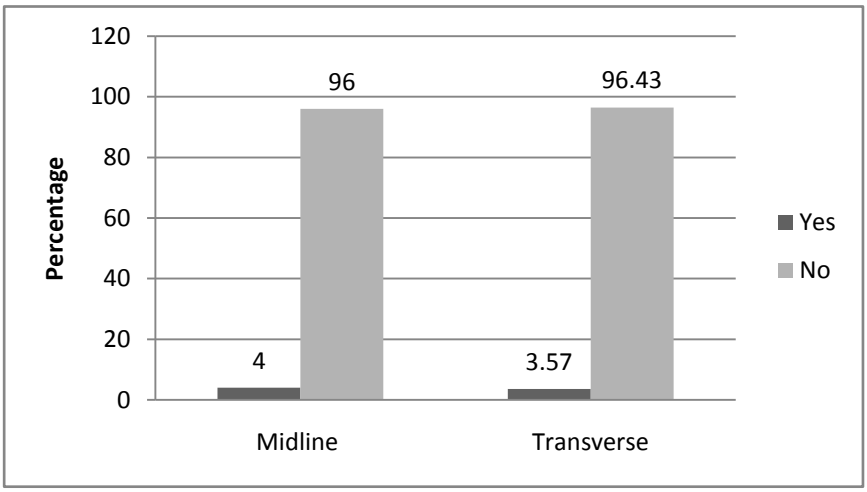


p value 0.935

Time to pass flatus

Bowel function recovery can be assessed by various methods. In this study we took 2 parameters time to pass stools and time to pass flatus. This time was calculated from the end of operation in hours. The midline group had a mean value of 78.39 hours for passage of flatus. The transverse group had a value of 63.85. The difference was not significant.

Table 19: Comparison of time taken to pass flatus between the midline and the transverse group

Group	n	Mean(hours)	S.D.	Minimum	Maximum	p - Value
Midline incision	23	78.39	64.08	36	360	**0.17**
Transverse incision	27	63.85	32.02	34	192	

Time to pass faeces

Midline group had a mean value of 99.43 hours for passage of faeces, transverse had a mean value of 86.85 hours only. However this difference was not significant.

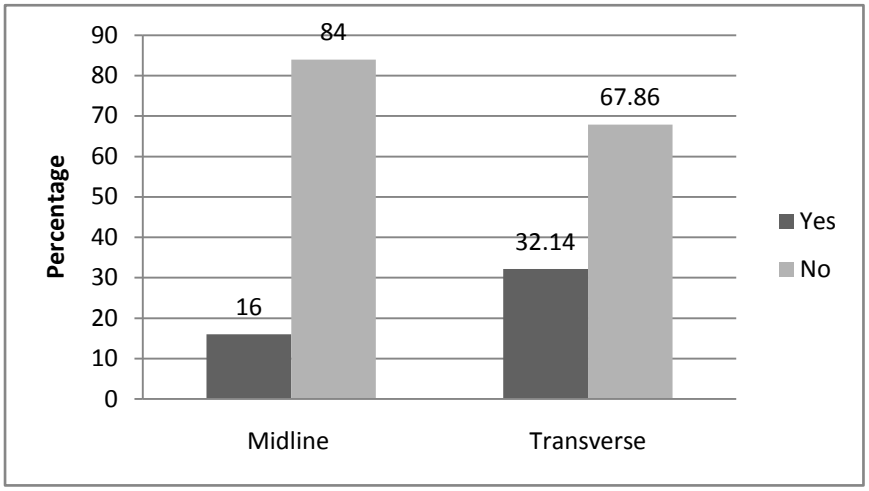
Table 20: Comparison of time taken to pass faeces between the midline and the transverse group

Group	n	Mean(hours)	S.D.	Minimum	Maximum	p – Value
Midline incision	23	99.43	65.42	43	384	**0.53**
Transverse incision	27	86.85	34.62	39	216	

Wound Infection

Wound infection was compared between both groups. Out of 25 patients in the midline group 4 had post operative wound infection. In the transverse group, out of 28 participants 9 had wound infection. Even though wound infection was higher in transverse group it was not significant. Most of the wound infection was diagnosed on 4th post operative day in both groups.

Fig.19: Bar diagram comparing wound infection between the midline and the transverse group



p value 0.17

Time to wound infection

Table 21: Comparison of time to wound infection between the midline and the transverse group

Group	n	Mean(days)	S.D.	Minimum	Maximum	p - Value
Midline incision	4	3.75	0.5	3	4	**0.29**
Transverse incision	9	4.22	0.83	3	6	

Table 22: Summary of outcomes

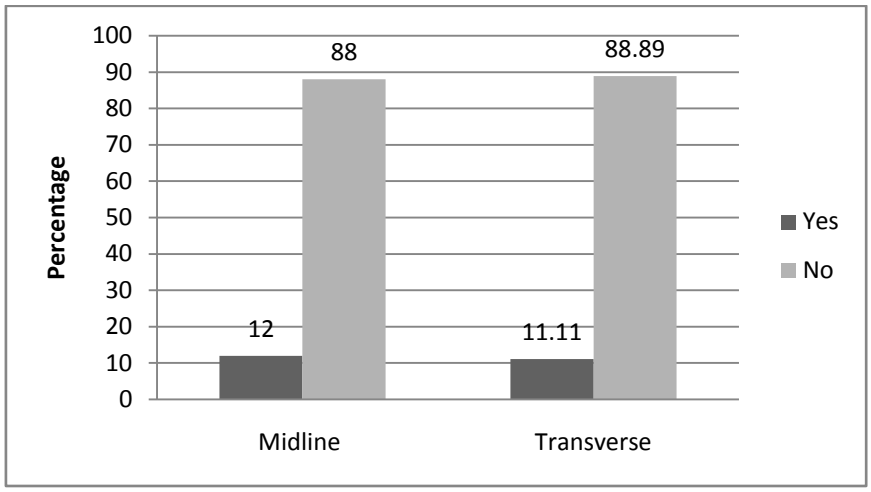
Outcome		Value measured	Midline incision group	Transverse incision group	P value
Duration of hospital stay		P50(p25,p75)	6 (5,6)	5 (4,6)	**0.0162**
Post op pain		Mean (min – max)	2.62 (1.2,4)	1.59 (0.6, 2.6)	**0.0001**
Pulmonary function recovery FVC	Pre op – 24 hours	Mean(95% C.I)	1.1 (0.86, 1.33)	0.75 (0.48, 1.02)	**0.05**
	Pre op – 72 hours	Mean(95% C.I)	1.25 (1, 1.5)	0.93 (0.64, 1.21)	0.08
	72- 24 hours	Mean(95% C.I)	0.13 (-0.10, 0.37)	0.109 (-0.14, 0.36)	0.88
Pulmonary infection		No (%)	2 (4)	2 (3.57)	0.935
Bowel function recovery	Time to pass flatus	Mean (min, max)	78.39(36, 360)	63.85 (34, 192)	0.17
	Time to pass stools	Mean (min, max)	99.43 (43, 384)	86.85 (39, 216)	0.53
Wound infection		No (%)	4 (16)	9(32.14)	0.17

Complications

Reoperation and re admission and their causes were compared in both groups. There were 3 reoperations in both groups; all were done for suspected anastamotic leak.

Reoperation

Fig 20: Bar diagram comparing no of readmissions between the midline and the transverse group



p value 0.92

Time to reoperation

In the midline group the mean operation post op day was 8 and in the transverse group it was 6. However this difference was not significant.

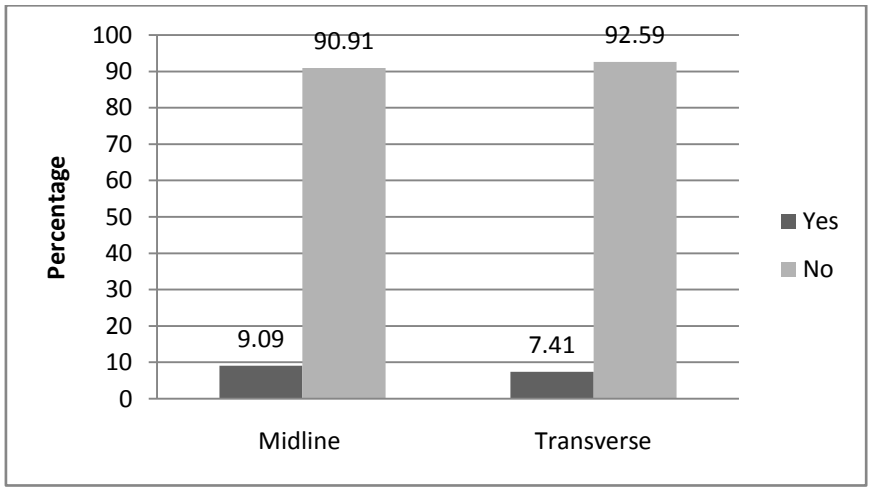
Table 23: Comparison of time to reoperation between the midline and the transverse group

Group	n	Mean(days)	S.D.	Minimum	Maximum	p - Value
Midline incision	3	8.33	3.51	5	12	**0.35**
Transverse incision	3	6	1.73	5	8	

Re admission

Readmissions were calculated in both the groups, the post operative day of readmission and the reason for readmission was documented. There were only 2 readmissions in both groups and their mean readmission day was 7 and 8 in midline and transverse group respectively. However this difference was not statistically significant.

Fig.21: Bar diagram showing percentage of re admissions in both the groups



p value 0.83

Re admission day

Table 24: Comparison of readmission post operative day between the midline and the transverse group

Group	n	Mean(days)	S.D.	Minimum	Maximum	p - Value
Midline incision	3	7.33	5.03	2	12	**0.77**
Transverse incision	2	8.5	0.71	8	9	

Discussion

In this study, we have compared transverse and midline incisions for colectomies. Literature on this suggests that transverse incisions are better in terms of post operative pain, pulmonary compromise, bowel function recovery, post operative complications and duration of hospital stay, but randomized trials are rare. The few trials that are available have small sample sizes.

This is the first such study with such a large sample size, in an Indian population, comparing all types of colectomies.

In this study, duration of hospital stay is considered as primary outcome. In our practice, we follow an Enhanced Recovery After Surgery (ERAS) programme for all patient who have major colorectal resection. While transverse incisions have been described as a component of ERAS, it is not clear how much this contributes to recovery and shorter hospital stay. We wished to study whether transverse incision further shortened hospital stay.

Parameters like post operative pain, pulmonary function compromise, wound infection, pulmonary infection and bowel function recovery were considered as secondary outcomes. They were considered secondary outcomes because they can influence the primary outcome.

Duration of hospital stay

Our primary outcome was duration of hospital stay. Duration of hospital day was calculated from the day of the operation till the date the patient was fit on discharge. To avoid confounding factors like participants willingness to stay longer or billing and insurance issues which could prolong the hospital stay, separate criteria were followed to assess the fitness for discharge. The patient should have been:

- afebrile for 24 hrs
- on a normal diet
- Passed stools and flatus post operatively
- off intra venous fluids

Among the 7 studies available in literature(10,12–17), 6 had duration of hospital stay as outcome(10, 12, 13,15–17). Brown and coworkers did not find any difference in duration of hospital stay (10). The other studies found significant difference in favour of transverse incision. Stipa calculated duration of hospital stay as the percentage of patients discharged in both groups on 8^{th} post operative day. Forty seven percent of patients with transverse incisions were discharged on the 8^{th} day in transverse group. The midline group had only 4% of the patients discharged on the 8^{th} post operative day (15). Lohsiriwat's study had a median hospital stay of 6 days in transverse group and 7.9 days in midline group(12).Theodosopoulos and coworkers had similar findings with median value of 5 days in the transverse group and 8 days in the midline group(17). Donati and Kam also found significantly lower hospital stay in transverse group(13,16).

None of the studies had any specific criteria to calculate duration of hospital stay. We used the above mentioned criteria to calculate the duration of hospital stay. After excluding the patients who had re operation during the same admission, midline group had 24 participants and transverse group had 25 participants. Midline group had a median hospital stay of 6 days. Transverse group had a median hospital stay of 5 days. This difference was statistically significant with a p value of 0.01.

The benefits are reduced hospital stay, decreased cost to the patient, decreased cost to the hospital, increased earnings for the hospital and reduced hospital infection. Transverse incision lead to all these benefits by contributing to reduced hospital stay.

It is to be noted that, within the ERAS programme in our institution, the mean duration of hospital stay for even the midline group is 6 days. This is much shorter than that reported in literature. Most studies have shown an 8 day hospital stay.

Pain

Among secondary outcomes, post operative pain was assessed using several parameters like

- visual analogue scale
- level of epidural insertion,
- change in epidural dosage and the reason,
- date of epidural removal, break- through analgesia if used,
- number of doses and the analgesics used,
- Post epidural analgesia, (whether tablet or injections) and use of any other mode of analgesia. In this study pain was assessed by a blinded assessor, not involved in the study. Pain score average was calculated each day and overall average was compared between both the groups.

Stipa found that 7 out of 12 patients in the transverse group had no or mild pain. In the midline group 11 out of 27 patients had no or mild pain. Lindgren compared pain between both groups at rest and after physical exercise. He found that the transverse group had less pain score as well as analgesic requirements (15).

Lohsiriwat found that the use of intravenous narcotics was less in the transverse group compared to midline group(12). Similar findings were mentioned for left hemicolectomy by Kam(16). Brown did not find any difference in pain score or analgesic requirements in his randomized controlled trial (10).

In our study we did not find any difference in analgesic requirements, break through analgesia or post epidural analgesia. The mean pain score was calculated after measuring scores twice a day. Scores were compared between both groups. *However, the pain score was significantly less in the transverse incision group. The midline group had a value of 2.62 and the transverse group had a score of 1.59 and this was statistically significant (0.0001).*

Pulmonary function recovery

Pulmonary function was assessed using spirometry. Three important parameters assessed in spirometry are FVC, FEV1 and FEV1/FVC. These help to distinguish restrictive from obstructive disease. Any abdominal operation will affect pulmonary function by impeding the movement of diaphragm. This type of impairment causes restrictive pulmonary compromise. Among the parameters assessed, FVC is the better indicator of restrictive pathology (21). Pulmonary function impairment due to an incision depends on how cranial the incision is and severity of post operative pain. Normally, midline incisions extend more cranially than transverse incisions.

In this study, we assumed that a transverse incision would cause less pulmonary impairment. To prove this, spirometry was done for participants' pre operatively, and then 24 hours and 72 hours post operatively. These parameters were compared and the difference was calculated.

In this study FEV1, FEV1/FVC or FVC did not show any statistically significant difference between the two groups.

In literature, only one study has assessed pulmonary function compromise by spirometry. Lindgren found that immediate post operative pulmonary function was compromised in both groups. However, the parameters recovered better in transverse group than midline group (14).

However, in our study FVC value difference between pre operative and 24 hours post operative in midline group was 1.10 and 0.75 in transverse group. *It showed a trend towards the transverse incision being better though this was not statistically significant.* The difference between pre operative and 72 hours did not show any significant difference between both groups.

This indicates that transverse incisions probably compromise pulmonary function less than midline incisions; however it was not statistically significant and was not reproducible after 72hours post operation. A larger sample size might produce a statistically significant difference.

Pulmonary infection

Pulmonary infection was diagnosed based on the criteria for hospital acquired pneumonia. This is one of the simplest criteria to diagnose pulmonary infection. In our study there were only 2 cases of pneumonia, one in each arm.

In literature there were 3 studies that analyzed pulmonary infection. Lohsiriwat had one pulmonary infection in midline group (12). Theodosopoulos had 7 pulmonary infection in midline group and 6 in transverse group (17). However this was not statistically significant. Lindgren concluded that transverse incision might produce less pulmonary complications (14). However in our study we did not find any difference.

Wound infection

Among wound related complications, wound infection and dehiscence are the early complications and incisional hernia a late complication. In this study we assessed only wound infection. Wound infection was diagnosed based on CDC criteria (28).

Lohsiriwat in his retrospective study had one wound infection in the transverse group and four in midline group. Theodosopoulos had two wound infections in each group. They did not find any statistically significant difference (17).

In our study, we had 9 out of 28 wound infection in transverse group and 4 out of 25 in midline group. This difference again was not significant.

Bowel function recovery

Recovery of bowel function is often difficult to assess. Assessment can be in several ways. It can be time taken to pass stools or flatus post operatively, time to start oral fluids, normal diet or stopping of intra venous fluids. Stipa assessed bowel function recovery by assessing time to pass stools and he did not find any significant difference (15). Lohsiriwat, Theodosopoulos, Brown and Donati compared bowel function recovery along with time to start oral fluid and solid diet(10,12,13,17). Donati found a statistically significant difference in bowel function recovery, starting of oral fluid and solid diet (13). The others did not find any significant difference. In our study we assessed time taken to pass flatus and faeces. The midline group had a mean value of 78.39 hours for passing flatus. The transverse group took 63.85 hours. Similarly, time to pass faeces also was faster in the transverse group (86.65 hours Vs 99.43 hours).

Even though there was a trend of early bowel function recovery in transverse group this difference was not significant (p value 0.17 and 0.53 respectively).

However, there were limitations with the use of time taken to pass flatus and faeces. Factors like anastomotic leaks or diarrhea secondary to pelvic collections can affect the outcome analysis.

Adequacy of oncological resection

Proximal and distal resection *margins* were compared in both arms. All proximal and distal margins were negative in both groups, implying that extent of resection is adequate with transverse incisions.

The number *of nodes* resected in both groups was compared. Transverse group had a mean value of 15.83 nodes. Midline group had 16.78. The p value was 0.87, which was not significant.

There was no difference in the adequacy of oncological resection between both groups.

TNM staging

TNM staging was also compared between both groups to see whether one group had early stage disease.

In the midline group 55% of tumours were T3 and in the transverse group 58% were T3. The difference was not significant (p-0.556).

Fifty percent of participants had N0 disease in midline group, and 54% participants had N0 disease in transverse group.

In midline group 52% of participants had TNM stage III disease, but transverse group 50% of patients had stage II disease. However this difference was not significant (p-0.5).

There was no difference in TNM stage distribution between both groups.

Length of incision

Shorter incisions will cause less post operative pain, less analgesic requirements and eventually will help in early recovery. So *length of incision* was assessed, and the transverse incision group had a mean length of 10.39 cm, the midline incision group had a mean length of 12.04cm. *The difference was statistically significant with a p value of 0.0003.*

Duration of operation

Duration of operation was also compared between the two groups. Duration of operation was shorter in the transverse incision group, though statistically insignificant.

Thus, transverse incisions are easy to perform, provide adequate access, do not compromise on oncological clearance, and are shorter in length than midline incisions.

Complications

Complications like wound infection and pulmonary infection were assessed as secondary outcomes. However other complications like re-operation, anastomotic leak and re admissions were also compared.

Both groups had 3 reoperations each and in all cases the reason for reoperation was suspected anastomotic leak. There was no significant difference in the post operative day in which the re- operation was done. In the same way, re admission for various reasons were compared in both the groups, the midline group had 3 readmissions and the transverse group had 2 re admissions, and the difference were not significant.

Limitations

During the course of this study, laparoscopic surgery was introduced in our unit. Hence we were not able to achieve our intended sample size as some of the patients had hemi or segmental colectomies laparoscopically.

Post operative analgesics requirement was assessed by using a fixed protocol.Perhaps it would have been better to assess the use of on demand analgesia requirement.

We had difficulty in assessing post operative bowel function recovery; factors like pelvic collection, electrolyte imbalance, use of opioids affected the bowel function recovery. Oral fluid intake and starting of solid diet was also not analyzed in our study, however these parameters were subjective and prone to bias.

Due to time constraint long term complications like incisional hernia were not assessed.

Conclusion

We compared midline and transverse incisions for hemi and segmental colectomies. It was a randomized controlled trial with 53 participants. There were 25 participants in the midline group and 28 in the transverse group.

Both groups did not show any difference in demographic profile and comorbid conditions. Type of anastomosis, benign malignant distribution, stoma creation duration of operation TNM stage distribution did not show any difference between both groups.

Our primary outcome (duration of hospital stay) was significantly lower in the transverse group. Among secondary outcomes, post operative pain was significantly less in the transverse incision group. However analgesic requirement was the same in both groups.

Pulmonary function recovery and bowel function recovery were not significantly different between both groups. However, there was a trend for early recovery in both parameters compared to midline incision in the transverse group.

Post operative complications like wound infection, pulmonary infection, re operation and re admission did not show any difference between both groups.

Length of incision was significantly shorter in the transverse incision group. Based on the above results we conclude that transverse incision is shorter in length, results in shorter hospital stay and less post operative pain compared to midline incision.

Annexure

Annexure - 1

INFORMATION SHEET

NAME OF THE PARTICIPANT: DATE: S.NO:

NAME OF THE STUDY: **Randomized controlled trial comparing the effect of transverse incision with midline incision on post operative recovery of patients undergoing elective hemi or segmental colectomy**

You have been diagnosed to have a disease of the large intestine and have been told that a part of your large intestine will have to be removed. This will require opening of the abdomen. The abdomen can be opened vertically in the midline or transversely. Normally this decision is taken by the operating surgeon and the vertical incision is the technique used most often. However, there are studies which have shown that a transverse incision is associated with less post operative pain, less lung compromise, early recovery from surgery and reduced hospital stay without any difficulty for the surgeon and may be better for the patient.

Since it is not known if transverse incisions are really better than vertical incisions, we would like to compare these two incisions in participants undergoing your type of operation. We plan to ask about 72 participants to take part in this study. Half of these participants will have a transverse incision and half will have a vertical incision. We will then compare the two groups of participants to see which group fared better.

This sheet will give you information you will need regarding this study. If you have any queries please feel free to ask the person whose name and contact details are given below.

If you are willing to take part in this study you will be enrolled into the study and you will either get a vertical or transverse incision. You will not know which incision you will get, but you have a 50:50 chance of a vertical or transverse incision. You will also be asked to undergo a few tests and asked a few questions. After all patients have had their operation, we will assess duration of hospital stay, pain after the operation, lung function, the function of your bowel and wound infection. We will also assess the function of your lungs by a test called 'Spirometry". This will be done 3 times, once before your operation and twice after your operation. This is a procedure where you will be asked to blow air into a machine. You will also have to undergo an extra blood test post operatively to check your total white blood cell count. This test will be helpful in diagnosing pulmonary infection early. Apart from these tests, you will be given the same care that all patients undergoing this procedure get. You will not be asked to bear the cost for these extra investigations and this will be done free of cost. However, you have to pay for your regular treatment.

By taking part in this study you will be helping us to assess if a transverse incision is better than a vertical incision. The information we obtain during this study may be used for publication in medical journals. However, your personal identity will not be revealed. You have right to refuse to take part in this study or withdraw from this study any time you wish to. That will not affect the treatment you receive for your disease. If you have any doubts at any time you can contact the following person

Annexure- 2

INFORMED CONSENT FORM

Study Title: TRANSVERSE Vs MIDLINE INCISION FOR RIGHT, LEFT AND SEGMENTAL COLECTOMIES

Study Number:_____ **Date:**

Participant's Name: _____ **Age:_____**

Please mark ✓ **in the space provided**

(i) I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the investigators will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes. [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness: _____

Date:_____/_____/_____

Name of the Witness: _____

Annexure- 3

PROFORMA

DEMOGRAPHIC PROFILE

1.NAME:_____ 2.AGE:_____ 3.SEX: M / F
4.S.NO:

5.ADDRESS:_____

_____

6.HT:_____ Ms 7.WT:_____KGs 8.BMI:_____

9.SMOKER: YES / NO 10.PACK YEARS:_____ 11.EX- SMOKER: YES / NO IF YES,
12.STOPPED HOW MANY MONTHS BACK:_____

13.ASTHMA: YES/ NO 14.COPD: YES / NO 15.ANY OTHER LUNG DISEASE:
_____ 15.DIABETES MELLITUS: YES / NO 16.PRE OP CHEMOTHERAPY: YES / NO
17.PRE OP RT: YES / NO

PRE OP EVALUATION

18.DIAGNOSIS:_____ 19.PLANNED
SURGERY:_____

20.DATE OF SURGERY:_____ 21.ANY PREVIOUS ABDOMINAL SURGERY: YES / NO

22.WHAT SURGERY:_____

INTRA OP ASSESSMENT

23. PERFORMED SURGERY:_____ ***24.OPERATION START TIME:_____***

25.OPERATION END TIME:_____ ***26.DURATION OF SURGERY :_____(MIN)***

27.LENGTH OF INCISION :_____(CM) ***28.ANASTOMOSIS: STAPLE / HAND***

29.EPIDURAL LEVEL: _____

PATHOLOGY:

30.NO.OF NODES REMOVED:_____ 31.TNM STAGE: _____

32.MARGIN TUMOUR INVOLVEMENT STATUS PROXIMAL: YES / NO 33.DISTAL: YES / NO

OUTCOME ASSESSSMENT: POST OP. PAIN – VISUAL ANALOG SCALE

DAY TIME	DAY 1	DAY2	DAY3	DAY4	DAY5	DAY6	DAY7	DAY8	DAY9	DAY10
34. 8:00 AM										
35. 4:00 PM										

EPIDURAL DOSE

DAY	DAY1	DAY2	DAY3
36.DOSE ML/HR			
37. DURATION IN HRS			
38.STOPPED?	Y / N	Y / N	Y / N
39.REASON			
40.STOPPED DURATION IN HRS			
41.CHANGE IN DOSE	Y / N	Y / N	Y / N
42.REASON			
43. CHANGED DOSE			
44. DURATION OF CHANGED DOSE			
45. TOTAL DURATION IN HRS			
46.TOTAL DOSE / DAY IN ML			

47.EPIDUAL REMOVED ON: _____POD

POST EPIDURAL ANALGESIA

DAY	DAY1	DAY2	DAY3	DAY4	DAY5	DAY6	DAY7	DAY8	DAY9	DAY10
48.DRUG										

BREAKTHROUGH ANALGESIA

DAY	DAY1	DAY2	DAY3	DAY4	DAY5	DAY6	DAY7	DAY8	DAY9	DAY10
49.DRUG										
50.DOSES										

51.ANY OTHER MODE OF ANALGESIA USED: YES / NO 52.IF YES WHAT:_____

PULMONARY FUNCTION: SPIROMETRY

VALUES	PRE OP	POST OP 24 HRS	POST OP 72HRS
53.VC			
54.FVC			
55.FEV1			
56.FEV1/FVC			

PULMONARY INFECTION:

DAY	DAY1	DAY2	DAY3	DAY4	DAY5	DAY6	DAY7	DAY8	DAY9	DAY10
57..TEMP> 38.3 C?										
58.TC > 10,000CELLS/MM3?										
59..PURULENT SPUTUM?										
60.CRITERIA FULFILLED?										
61.CHEST X RAY DONE?										
62.POS. FINDING										
63.RPT X RAY DONE?										
64.CONFIRMED?										
65.PUL. INF. PRESENT?										

BOWEL FUNCTION RECOVERY

PASSED FLATUS AT:66.DATE_____67.TIME_____68.TIME TAKEN : _____ (IN HRS)

PASSED FAECES AT: 69.DATE_____70.TIME_____ 71.TIME TAKEN : _____ (IN HRS)

WOUND INFECTION

DAY	DAY3	DAY4	DAY5	DAY6	DAY7	DAY8	DAY9	DAY10	11-30 DAYS
72.WOUND INFECTION?									

HOSPITAL STAY

73.DECLARED FIT FOR DISCHARGE ON:_____

74.DURATION OF HOSPITAL STAY :_____(DAYS)

[CALCULATED FROM OPERATION DATE TO THE DAY PATIENT FIT TO BE DISCHARGED]

75.REOPERATION: YES / NO IF YES 76.DAY: _____ POST OP. DAY

77.REASON:_____

78.READMISSION: YES / NO IF YES 79.DAY: _____ POST OP. DAY

80.REASON:_____

81. ALLOCATION NO: _____

REFERENCES

REFERENCES

1. Grantcharov TP, Rosenberg J. Vertical compared with transverse incisions in abdominal surgery. European Journal of Surgery. 2001;167(4):260–7.

2. Michael J. Zinner, MD, FACS Stanley W. Ashley, MD, FACS. Maingot's Abdominal Operations > Chapter 23. Tumors of the Colon >Epidemiology. 11TH EDITION.

3. Colorectal cancer in India: controversies, enigmas and primary prevention K. M. Mohandas. Indian J Gastroenterol (Jan–Feb 2011) 30(1):3–6.

4. Norman S. Williams MS FRCS FMed Sci Christopher J.K. Bulstrode MCh FRCS(Orth) P. RONAN O'CONNELL MD FRCSI FRCPS(Glas) Bailey & Love's SHORT PRACTICE of SURGERY. 25th edition.

5. Charles J. Yeo, MD Samuel D. Gross Professor and Chair, Department of Surgery, Thomas Jefferson University, Philadelphia, Pennsylvania. Shackelford's Surgery of the Alimentary Tract>TREATMENT OF PRIMARY COLON AND RECTAL CARCINOMA. 6th edition.

6. Michael J. Zinner, MD, FACS Stanley W. Ashley, MD, FACS. Maingot's Abdominal Operations > Chapter 23. Tumors of the Colon >Surgery General Technical Principles. 11th edition.

7. Health D of. Enhanced recovery research and resources [Internet]. [cited 2012 Sep 16]. Available from: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/Electivecare/Enhancedrecovery/DH_115765

8. Kahokehr AA, Sammour T, Sahakian V, Zargar-Shoshtari K, Hill AG. Influences on length of stay in an enhanced recovery programme after colonic surgery. Colorectal Dis. 2011 May;13(5):594–9.

9. Brown SR, Goodfellow PB. Transverse verses midline incisions for abdominal surgery. Cochrane Database Syst Rev [Internet]. 2005 [cited 2012 Aug 18];4. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005199.pub2/pdf/standard

10. Brown SR, Goodfellow PJ, Adam IJ, Shorthouse AJ. A randomised controlled trial of transverse skin crease vs. vertical midline incision for right hemicolectomy. Tech Coloproctol. 2004 Mar;8(1):15–8.

11. J.Jeekel, M. van ;t Riet JWAB. ABDOMINAL INCISIONS : TECHNIQUES AND POSTOPERATIVE COMPLICATIONS. Scandinavian Journal of Surgery. 2002;315–21.

12. Lohsiriwat V, Lohsiriwat D, Boonnuch W, Chinswangwatanakul V, Akaraviputh T, Methasade A, et al. Comparison between midline and right transverse incision in right hemicolectomy for right-sided colon cancer: a retrospective study. J Med Assoc Thai. 2009 Aug;92(8):1003–8.

13. Donati D, Brown SR, Eu KW, Ho YH, Seow-Choen F. Comparison between midline incision and limited right skin crease incision for right-sided colonic cancers. Tech Coloproctol. 2002 Apr;6(1):1–4.

14. Lindgren PG, Nordgren SR, Öresland T, Hulten L. Midline or transverse abdominal incision for right-sided colon cancer—a randomized trial. Colorectal Disease. 2001;3(1):46–50.

15. Stipa F, Barreca M, Lucandri G, Fernades E, Mercantini P, Meli L, et al. [Transverse minilaparotomy as an access route in right colon disease: a valid alternative to midline laparotomy]. Chir Ital. 2000 Feb;52(1):91–6.

16. Kam MH, Seow-Choen F, Peng XH, Eu KW, Tang CL, Heah SM, et al. Minilaparotomy left iliac fossa skin crease incision vs. midline incision for left-sided colorectal cancer. Tech Coloproctol. 2004 Aug;8(2):85–8.

17. Theodosopoulos T, Yiallourou AI, Dafnios N, Polymeneas G, Papaconstantinou I, Staikou C, et al. Right Kocher's incision: a feasible and effective incision for right hemicolectomy. A retrospective study. World journal of surgical oncology. 2012 Jun 7;10(1):101.

18. Zhong B. How to Calculate Sample Size in Randomized Controlled Trial? J Thorac Dis. 2009 Dec;1(1):51–4.

19. By D Machin, M Campbell, P Fayers & A Pinol. Sample Size Tables for Clinical Studies (2nd Edition, 1997) - [ISBN 0-86542-870-0]. 2nd ed. published by Blackwell Science Ltd;

20. Daabiss M. American Society of Anaesthesiologists physical status classification. Indian J Anaesth. 2011;55(2):111–5.

21. Pulmonary function tests - PubMed Health [Internet]. [cited 2012 Aug 26]. Available from: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0004306/

22. David Shen. Randomization in clinical trials. pharma surg 2006.

23. Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. Lancet. 2002 Feb 16;359(9306):614–8.

24. Y H Chan. Randomised controlled trials -essentials. Singapore Med J 2003 Vol 44(2) : 060-063. 2003; 25. Bupivacain and Fentanyl for Epidural administration. Liverpool Health Service Intensive Care Unit; 2002.

26. Kollef MH. What is ventilator-associated pneumonia and why is it important? Respir Care. 2005 Jun;50(6):714–721; discussion 721–724.

27. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. Am. J. Respir. Crit. Care Med. 2005 Feb 15;171(4):388–416.

28. Guideline for prevention of surgical site infection. JULY 2000 BULLETIN OF THE AMERICAN COLLEGE OF SURGEONS. 2000;

29. AJCC Cancer Staging Manual (Sixth ed.). Springer-Verlag New York, Inc.. 2002.

30. Wikipedia contributors. Body mass index [Internet]. Wikipedia, the free encyclopedia. Wikimedia Foundation, Inc.; 2012 [cited 2012 Sep 17]. Available from: http://en.wikipedia.org/w/index.php?title=Body_mass_index&oldid=512823088

31. Healthy Weight: Assessing Your Weight: BMI: About Adult BMI | DNPAO | CDC [Internet]. [cited 2012 Sep 17]. Available from: http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html

32. Bobbio A, Chetta A, Carbognani P, Internullo E, Verduri A, Sansebastiano G, et al. Changes in pulmonary function test and cardio-pulmonary exercise capacity in COPD patients after lobar pulmonary resection. Eur J Cardiothorac Surg. 2005 Nov;28(5):754–8.

33. Enright PL, Lebowitz MD, Cockroft DW. Physiologic measures: pulmonary function tests. Asthma outcome. Am. J. Respir. Crit. Care Med. 1994 Feb;149(2 Pt 2):S9–18; discussion S19–20.

34. Crapo RO. Pulmonary-function testing. N. Engl. J. Med. 1994 Jul 7;331(1):25–30.

35. Terranova A. The effects of diabetes mellitus on wound healing. Plast Surg Nurs. 1991;11(1):20–5.

36. Payne WG, Naidu DK, Wheeler CK, Barkoe D, Mentis M, Salas RE, et al. Wound Healing in PatientsWith Cancer. Eplasty [Internet]. 2008 Jan 11 [cited 2012 Sep 17];8. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2206003/

37. Jyrki Kössi*,1, Markku Luostarinen1 and Matti Laato2. Laparoscopic and Open Colorectal Surgery in Previously Operated Patients is Associated with Considerable Need for Adhesiolysis. The Open Surgery Journal, 2010, 4, 7-10.

38. Theadom A, Cropley M. Effects of preoperative smoking cessation on the incidence and risk of intraoperative and postoperative complications in adult smokers: a systematic review. Tob Control. 2006 Oct;15(5):352–8.

39. Groth SS, Whitson BA, Kuskowski MA, Holmstrom AM, Rubins JB, Kelly RF. Impact of preoperative smoking status on postoperative complication rates and pulmonary function test results 1-year following pulmonary resection for non-small cell lung cancer. Lung Cancer. 2009 Jun;64(3):352–7.

Variable names and codes

v2 age ##
v3 sex # (1-male 2-female)
v4 s.no ##
v5 address _____
v6 ht #.## (metres)
v7 wt ### (kgs)
v8 bmi ##.#
v9 smoker # (1 yes 2 no)
v10 pack years ##
v11 ex smoker # (1 yes 2 no)
v12 stopped months ###
v13 asthma # (1 yes 2 no)
v14 copd # (1 yes 2 no)
v15 any other _____
v16 dm # (1 yes 2 no)
v17 preop chemo # (1 yes 2 no)
v171 pre op rt # (1 yes 2 no)
v18 diagnosis # (1 carcinoma 2 benign)
v19 planned surgery # 1 right 2 ex right 3 left 4 tran 5 sigmoid
v20 dos <dd/mm/yyyy>
v21 prev abd surgery # (1- yes 2 - no)
v22 what sx _____
v23 sx # (1 right 2 ex right 3 left 4 tran 5 sigmoid)
v24 stoma # (1 yes 2 no)
v251 sx start time ##.## hrs
v252 sx end time ##.## hrs
v253 duration ### min
v26 length ## cm
v27 anastomosis # 1 hand 2 staple
v28 epidural level # 1 t7 2 t8 3 t9 4 t10 5 t11 6 t12 7 l1 8 l2
v29 no of nodes ##
v30 t #
v31 n #
v32 m #
v33 stage #_
v34 prox margin # (1 yes 2 no)
v35 distal margin # (1 yes 2 no)
V361 VAS D1 #
V362 VAS D2 #
V363 VAS D3 #
V364 VASD4 #
V365 vas d5 #
v366 vas d6 #
v367 vas d7 #
v368 vas d8 #
v369 vas d9 #
v37 ave vas #.#
v381 epid1 #.# ml/hr
v382 epid2 #.# ml/hr
v383 epid3 #.# ml/hr
v391 st/ch d1 # (1 yes 2 no d1)
v392 st/ch d2 # (1 yes 2 no d2)
v393 st/ch d3 # (1 yes 2 no d3)
v401 reason # (1 not fun 2 hypo 3 paralysis 4 othr 5 inadequate 6 less pain d1)
v402 reason # (1 not fun 2 hypo 3 paralysis 4 othr 5 inadequate 6 less pain d2)
v403 reason # (1 not fun 2 hypo 3 paralysis 4 othr 5 inadequate 6 less pain d3)
v411 total dose ### ml d1
v412 total dose ### ml d2
v413 total dose ### ml d3

v414 total ### ml
v421 total duration ## hrs d1
v422 total duration ## hrs d2
v423 total duration ## hrs d3
v424 total ### hrs
v431 total dose #.# ml/hr d1
v432 total dose #.# ml/hr d2
v433 total dose #.# ml/hr d3
v44 avr t.d #.#
v45 epidural removed # pod
v461 pea # (0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d1
v462 pea # (0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d2
v463 pea # (0 nil1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d3
v464 pea # (0 nil1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d4
v465 pea # (0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d5
v466 pea # (0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d6
v467 pea # (0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d7
v468 pea # (0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d8
v469 pea # (0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d9
v471 bta # (0 nil1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d1
v472 bta # 0 nil1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1) d2
v473 bta # 0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1d3
v474 bta # 0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1d4
v475 bta # 0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1d5
v476 bta # 0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1d6
v477 bta # 0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1d7
v478 bta # 0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1d8
v479 bta # 0 nil 1 t. voveran 2 t. tram 3 inj.vov 4 inj tram 5 inj mor 6 vov patch 7 fen patch 8 others 9 more than 1d9
v48 pain _____
v491 spiro pre op # 1 done 2 not done
v492 reason # 1 icu 2 not cooperative 3 missed 4 others
v493 pod1 spiro # 1 done 2 not done
v494 reason # 1 icu 2 not coperative 3 missed 4 others
v495 pod 3 spiro # 1 done 2 not done
v496 reason # 1 icu 2 not cooperative 3 missed 4 others
v501 fvc #.## po
v502 fvc #.## pod1
v503 fvc #.## pod3
v511 fev1 po #.##
v512 fev1 pod1 #.##
v513 fev1 pod3 #.##
v521 fev1/fvc po ##.#

v522 fev1/fvc pod1 ##.#
v523 fev1/fvc pod3 ##.#
v53 temp > 38.3 # 1 yes 2 no
v54 tc > 10,000 # 1 yes 2 no 3 not done
v541 sputum productin # 1 yes 2 no
v55 criteria fulfilled # 1 yes 2 no 3 not adequate
v56 cxr # 1 done 2 n.d
v561 findings _____
V562 RPT XRAY # 1 done 2 notdone
v563 findings _____
v57 pul inf # 1 yes 2 no
v58 other cause fever _____
v59 passed flatus <dd/mm/yyyy>
v60 time ##.## hrs
v61 total duration ### hrs
v62 passed stools <dd/mm/yyyy>
v63 time ##.## hrs
v64 total duration ### hrs
v65 wound inf # 1 yes 2 no
v66 wound inf dx pod ##
v67 declared fit <dd/mm/yyyy>
v68 hos stay ## days
v69 reoperation # 1 yes 2 no
v70 reop pod ##
v71 reason _____
v72 readmission # 1 yes 2 no
v73 readmission pod ##
v74 reason _____
v75 allocation no # 1-m 2-f

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	s.no	v2	v3	v4	v5	v6	v7	v8	v9	v10	v11	v12	v13	v14	v15	v16	v17	v171	v18
2	1	30	1	1	WEST BENGAL	1.65	50	18.4	2		2		2	2		2	2	2	1
3	2	55	2	2	WEST BENGAL	1.48	37	16.9	2		2		2	2		2	2	2	1
4	3	26	2	3	WEST BENGAL	1.48	37	16.9	2		2		2	2		2	2	2	1
5	4	33	2	4	ASSAM	1.31	43	25.1	2		2		2	2		2	2	2	1
6	5	64	1	5	JHARKAND	1.6	69	27	2		2		2	2		2	2	2	1
7	6	60	1	6	TAMILNADU	1.62	76	28.6	2		2		2	2		1	2	2	1
8	7	52	1	7	JHARKAND	1.69	70	24.5	2		2		2	2		2	2	2	1
9	8	55	1	8	MIZORAM	1.72	80	27	2		2		2	2		1	2	2	1
10	9	57	2	9	WEST BENGAL	1.55	47	19.6	2		2		2	2		2	2	2	1
11	10	60	2	10	TAMILNADU	1.51	45	19.6	2		2		2	2		2	2	2	1
12	11	30	2	11	WEST BENGAL	1.44	42	20.3	2		2		2	2		2	2	2	2
13	12	36	1	12	bihar	1.64	53	19.7	2		2		2	2	no	2	2	2	2
14	13	66	2	13	ANDHRA PRAD	1.44	53	25.6	2		2		2	2	CA ENDOM	1	2	1	1
15	14	69	1	14	TAMIL NADU	1.42	41	20	2		2		2	2		1	2	2	1
16	15	54	1	15	WEST BENGAL	1.59	51	20.2	2		2		2	2		1	2	2	1
17	16	30	2	16	tamilnadu	1.52	52	22.5	2		2		2	2		2	2	2	1
18	17	48	1	17	west bengal	1.54	54	22.8	2		2		2	2		2	2	2	1
19	18	60	1	18	JHARKHAND	1.72	74	25	2		1	174	2	2		1	2	2	1
20	19	52	1	19	MEGHALAYA	1.57	70	28.4	2		2		2	2		2	2	2	1
21	20	31	2	20	BANGLADESH	1.53	56	23.9	2		2		2	2		2	2	2	1
22	21	59	1	21	WEST BENGAL	1.61	65	25.1	2		1	24	2	2		2	2	2	2
23	22	35	1	22	WEST BENGAL	1.64	47	17.5	2		1	12	2	2		2	2	2	1
24	23	40	1	23	WEST BENGAL	1.62	50	19.1	2		2		2	2		2	2	2	1
25	24	59	2	24	BANGLADESH	1.48	60	27.4	2		2		2	2		2	2	2	1
26	25	37	2	25	WEST BENGAL	1.51	47	20.6	2		2		2	2		2	2	2	1
27	26	35	1	26	WEST BENGAL	1.73	63	21	2		2		2	2		2	2	2	1
28	27	62	1	27	JHARKHAND	1.69	55	19.3	2		2		2	2		2	2	2	1
29	28	70	2	28	WEST BENGAL	1.48	37	16.9	1	25	2		2	1	HONEY CO	2	2	2	1
30	29	51	2	29	WEST BENGAL	1.52	56	24.2	2		2		2	2		2	1	2	1
31	30	30	2	30	WEST BENGAL	1.5	35	15.6	2		2		2	2		2	2	2	2
32	31	57	1	31	WEST BENGAL	1.65	70	25.7	2		2		2	2		2	2	2	1
33	32	34	1	32	BANGLADESH	1.72	62	21	2		2		2	2		2	2	2	1
34	33	40	2	33	WEST BENGAL	1.6	67	26.1	2		2		2	2		2	2	2	1
35	34	25	2	34	TAMILNADU	1.39	45	23.3	2		2		2	2		2	2	2	2
36	35	55	2	35	west bengal	1.48	49	22.4	2		2		2	2		2	2	2	1
37	36	43	2	36	jharkhand	1.47	36	16.7	2		2		2	2		2	2	2	2
38	37	56	1	37	WEST BENGAL	1.74	81	26.8	1	20	2		2	2		2	2	2	2
39	38	43	2	38	WESTBENGAL	1.52	52	22.5	2		2		2	2		2	2	2	1
40	39	16	1	39	TAMILNADU	1.34	25	13.9	2		2		2	2		2	2	2	2
41	40	49	2	40	JHARKHAND	1.56	42	17.3	2		2		2	2		2	2	2	2
42	41	56	1	41	ORISSA	1.67	55	19.7	2		2		2	2		2	2	2	1
43	42	69	1	42	WEST BENGAL	1.63	59	22.2	2		1	120	2	2		2	2	2	1
44	43	39	1	43	WEST BENGAL	1.58	63	25.2	2		1	2	2	2		2	2	2	2
45	44	57	1	44	ARUNACHAL P	1.59	55	21.8	2		2		2	2		2	2	2	1
46	45	46	1	45	TAMILNADU	1.69	67	23.5	2		2		2	2		2	2	2	1
47	46	70	1	46	TAMILNADU		48		2		2		2	2		2	2	2	1
48	47	41	1	47	WEST BENGAL	1.55	55	20.8	1	10	2		2	2		1	2	2	1
49	48	52	1	48	bangladesh		60		2		2		2	2		1	2	2	1
50	49	55	2	49	JHARKHAND	1.5	62	27.6	2		2		2	2		2	2	2	1
51	50	42	1	50	WEST BENGAL	1.69	61	22.4	2		2		2	2		2	2	2	1
52	51	51	1	51	JHARKHAND	1.7	54	18.7	2		2		2	2		2	2	2	1
53	52	53	1	52	WEST BENGAL	1.58	50	20	1	30	2		2	1		2	2	2	1
54	53	73	1	53	TAMILNADU	1.5	42	18.7	1	50	2		2	1		2	2	2	1

	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL
1	v19	v20	v21	v22	v23	v24	v251	v252	v253	v26	v27	v28	v29	v30	v31	v32	v33	v34	v35
2	1	26/08/2010	1	APPENDICECTO	1	2	14.4	16.25	105	12	1	4	13	3	2	0	3	B	2
3	1	02/09/2010	1	GYNACOLOGY	1	2	13.55	16.45	150	10	1	3	6	3	1	0	3	B	2
4	2	16/09/2010	1	LSCS	1	2	11.3	14	150	12	1	5	14	3	2	0	3	B	2
5	2	11/10/2010	1	LSCS	2	2	8	11	180	15	1	5	13	3	1	0	3	B	2
6	1	21/10/2010	2		2	2	8.15	10.45	150	10	1	4	13	3	0	0	2	A	2
7	1	01/11/2010	1	HERNIOPLASTY	1	2	11	14	180	12	1	5	9	3	2	0	3	B	2
8	1	22/11/2010	2		1	2	10	12.3	150	10	1	7	14	3	2	0	3	B	2
9	1	09/12/2010	2		1	2	8.1	10.1	120	10	2	6	37	4	0	0	2	B	2
10	1	06/01/2011	2		2	2	10.1	12.4	150	8	1	3	15	3	0	0	2	A	2
11	3	10/12/2011	1	TUBECTOMY	3	2	10	11.3	90	10	2	5	11	2	0	0	1		2
12	3	13/01/2011	1	TUBECTOMY	3	2	13.15	15.15	120	8	1	7							
13	1	20/01/2011	1	appendicectom	1	2	8.15	10.15	120	20	1	6							
14	1	27/01/2011	1	TAH + BSO	1	2	13	16	180	11	1	4	8	3	0	0	2	A	2
15	1	27/01/2011	1	LSCS	2	2	13.15	16.3	195	12	1	2	18	4	2	0	3	C	2
16	3	31/01/2011	2		3	2	10	13	180	13	1	5	14	4	0	0	2	C	2
17	1	10/02/2011	2		1	2	8	11	180	12	1	4	15	4	2		3	c	2
18	1	10/03/2011	2		1	2	11	13.3	150	12	2	4	15	3	0	0	2	a	2
19	1	04/04/2011	2		1	2	8.15	10.4	145	10	2	4	19	4	0	0	2	B	2
20	5	07/04/2011	2		5	2	12	15.45	240	13	2	7							
21	1	07/04/2011	2		2		14.3	16.45	135	10	1	3	11	4	2	0	3	C	2
22	1	02/05/2011	2		1	1	9	11.3	150	11		3							
23	1	12/05/2011	2		1	2	14.4	16.1	90	10	1	3	11	0	0	0			2
24	1	06/06/2011	2		1	2	13	14.3	90	10	2	4	22	3	0	0	2	A	2
25	2	30/06/2011	2		1	2	10	12.45	165	10	1	6	18	4	0	0	2	B	2
26	1	30/06/2011	1	GYNACOLOGIC	1	2	9	10.3	90	9	1	5	12	3	0	0	2	A	2
27	1	11/07/2011	2		1	2	10	12	120	10	1	3	15	3	1	0	3	B	2
28	1	01/08/2011	2		1	2	14.45	17	135	9	1	4	27	3	0	0	2	A	2
29	1	22/08/2011	2		1	1	12	14	120	13	1	5	19	3	0	0	2	A	2
30	1	22/08/2011	1	TAH+ BSO	1	2	12.4	15.5	190	18	1	5	10	4	1	0	3	B	2
31	1	08/09/2011	2		1	2	13	15.3	150	13	1	4							
32	1	09/09/2011	1	APPENDICECTO	1	2	12	14	120	12	1	5	13	4	0	0	2	B	2
33	1	15/09/2011	2		1	2	13	15	120	15	1	4	22	4	2	0	3	C	2
34	3	19/09/2011	1	APPENDICECTO	3	2	8.3	11.3	180	13	1	5	8	4	1	0	3	B	2
35	2	22/09/2011	1	HERNIA REPAIR	1	2	14.3	17	150	12	1	5							
36	1	23/09/2011	2		1	2	13	15	120	10	1	3	12	3	0	0	2	a	2
37	1	10/10/2011	2		1	2	13.3	16	150	10	1	1							
38	1	21/11/2011	2		1	2	9	11	120	10	1	4							
39	1	08/12/2011	1	lscs sterlization	1	2	13	15	120	11	1	2	14	3	1		3	b	2
40	1	27/01/2012	2		1	2	12	13.3	90	9	1	4							
41	1	20/01/2012	1	LSCS	1	1	12.3	15	150	10		4							
42	1	23/02/2012	2		1	2	10	12.3	150	14	1	4	13	3	1	0	3	B	2
43	2	01/03/2012	2		2	1	12.3	15	150	11	1	4	11	4	1	0	3	B	2
44	1	12/03/2012	1	APPENDICECTO	1	2	13.5	16.3	160	10	1	3							
45	1	16/03/2012	1	APPENDICECTO	1	2	15	16.3	90	8	1	4	16	3	1	0	3	B	2
46	1	02/04/2012	2		1	2	13	15	120	10	1	4	13	3	1	0	3	B	2
47	2	02/04/2012	2		1	2	11	13.15	150	11	1	1	18	1	0	0	1		2
48	2	18/04/2012	2		1	2	10	12.3	150	12	1	2	38	3	1	0	3	B	2
49	1	23/04/2012	1	laparoscopic ch	1	2	14.3	16.3	120	10	1		17	3	0	0	2	a	2
50	1	25/04/2012	2		1	2	10	12	120	11	1	4	31	2	0	0	1		2
51	1	03/05/2012	2		1	2	12.3	15	150	10	2	7	19	3	0	0	2	A	2
52	1	28/05/2012	2		1	2	14.3	16	90	10	2	8	18	3	0	0	2	A	2
53	1	04/07/2012	2		1	2	12	14.3	150	9	1	3	17	4	0	0	2	B	2
54	1	04/07/2012	2		1	2	15	17.3	150	11	1	3	23	4	2	0	3	C	2

	AM	AN	AO	AP	AQ	AR	AS	AT	AU	AV	AW	AX	AY	AZ	BA	BB	BC	BD	BE	BF
1	v36	v361	v362	v363	v364	v365	v366	v367	v368	v369	v37	v381	v382	v383	v391	v392	v393	v401	v402	v403
2	2	7	8	3	1	1					4	7	5	5		1			2	
3	2	4	2	1	0						1.7	5	5	5						
4	2	1	1	1	0						0.7	5	5	5	2	2	2			
5	2	3	1	5	2	2					2.6	5	3	3	2	1	2		2	
6	2	1	3	2	3	6					3	5	5	5	2	2	2			
7	2	7	2	2	1	3					3	4	4	4	2	2	2			
8	2	2	4	3	3	3					3	5	5	5	2	2	2			
9	2	4	2	1	2	0					1.8	5	4	4	1			2		
10	2	2	4	3	1						2.5	5	6	6	1			5		
11	2	0	2	2	1	1					1.2	5	5	5	2	2	2			
12		2	2	1	2	1	2				1.6	4	4		2	2	1			1
13		3	3	1	1	0					1.6	5	6	6	1	1	1	6	2	2
14	2	1	2	3	3	4					2.6	5	4	4	2	1	2		6	
15	2	2	1	0	2						1.2	6	5	5	2	1	2		6	
16	2	2	5	5	3						3.7	7	7	0	2	1			1	
17	2	2	1	1	1	1					1.2	3.5	2.5	3.5	2	1	1		2	5
18	2	2	2	1	2	1	1				1.5	5	5	5	2	2	2			
19	2	2	1	1	1						1.2	5	5	5	2	2	2			
20		4	2	2	1						2.2	5	5	5	2	2	2			
21	2	2	2	1	1	1					1.4	5	5	5	2	2	2			
22		4	3	3	2						3	5	6	6	2	1	2		5	
23	2	6	2	1	1	1					2.2	5	8	8	1	2	2	5		
24	2	6	3	2	1						3	5	5	5	2	2	2			
25	2	2	1	2	1						1.5	5	5	5	2	2	2			
26	2	2	2	1	1						1.5									
27	2	3	2	1	1						1.7	5	4	3	2	1	1		6	6
28	2	1	2	1	0	1					1	5	5	5	2	2	2			
29	2	4	3	5	4						4	5	5	5	2	2	2			
30	2	6	1	1	1						2.2	5			1			1		
31		6	3	3	2						3.5	5			1			1		
32	2	4	3	2	1						2.5	6	5	5	1	2	2	2		
33	2	2	1	1	1						1.2	5	5	5	2	1	2		4	
34	2	5	5	3	2	1					3.2	5	7	7	1	2	2	5		
35		2	2	2	3						2.2	4	4	4	2	2	2			
36	2	1	2	1	1	1					1.2	5	5	5	2	2	2			
37		2	5	1	1						2.2	4	3	3	2	1			2	
38		3	2	1	1						1.7	4	4	6	2	2	1			5
39	2	2	2	1	1	1					1.4	5	3	3	2	1	2		2	
40		4	3	2	1	0					2	4			1			1		
41		4	3	3	1	0					2.2	5			1			2		
42	2	4	3	2	1	1					2.2	5			1			2		
43	2	2	1	1	1	1					1.2	5	5	5	2	2	2			
44		1	0	0	2						0.6	5	4	4	2	1	2		6	
45	2	3	2	2	2	2					2.2	4	4	4	2	2	2			
46	2	2	1	3	2	3					2.2	5	5	5	2	2	2			
47	2	2	3	1	1	0					1.4	4	3	5	1	1	1	2	6	6
48	2	4	3	2	3	2					2.8	5	5	5	2	2	2			
49	2	3	2	1	1	2					1.8									
50	2	4	3	3	2	1					2.6	5	5	5	2	2	2			
51	2	3	2	2	3	2					2.4	5	5	5	2	2	2			
52	2	3	1	1	1	1					1.4	4	5	5	2	1	2		5	
53	2	2	1	1	1	1					1.2	5	5	5	2	2	2			
54	2	4	4	3	2	2					3	5			1			2		

	BG	BH	BI	BJ	BK	BL	BM	BN	BO	BP	BQ	BR	BS	BT	BU	BV	BW	BX	BY	BZ	CA	CB
1	v411	v412	v413	v414	v421	v422	v423	v424	v431	v432	v433	v44	v45	v461	v462	v463	v464	v465	v466	v467	v468	v469
2	84	152	120	356	12	24	24	60	7	6.1	5	6	4				1					
3	60	120	120	300	12	24	24	60	5	5	5	5	4				9	1	1			
4	70	120	120	310	14	24	24	62	5	5	5	5	4				1	1				
5	90	78	72	240	18	24	24	66	5	3.2	3	3.7	4				3					
6	95	120	120	335	19	24	24	67	5	5	5	5	4				3	3				
7	60	96	96	252	15	24	24	63	4	4	4	4	4				1	1	1			
8	85	120	120	325	17	24	24	65	5	5	5	5	4				3	3	3			
9	82	96	96	274	18	24	24	66	4.3	4	4	4.1	4				3	3				
10	92	144	144	380	16	24	24	64	5.7	6	6	5.9	4				1	1	1			
11	90	120	120	330	18	24	24	66	5	5	5	5	4				1	1				
12	48	96	8	152	12	24	24	60	4	4	4	4	3			5	3	1				
13	104	120	120	344	18	20	20	58	5.7	6	6	5.9	4	0	0	0	0	0	0			
14	65	98	96	259	13	24	24	61	5	4	4	4.3	4				5	4	4			
15	72	123	120	315	12	24	24	60	6	5.1	5	5.3	4				3	3	1			
16	112	21		133	16	3		19	7	7		7	2		5	5	5	1				
17	63	64	80	207	18	24	24	66	3.5	2.6	3.3	3.1	4				5	5	8			
18	80	120	120	320	16	24	24	64	5	5	5	5	4				1	1	1			
19	95	120	120	335	19	24	24	67	5	5	5	5	4				3	3	2	2		
20	70	120	120	310	14	24	24	62	5	5	5	5	4				3	1	1			
21	65	120	120	305	13	24	24	61	5	5	5	5	4				3	1	1			
22	90	141	144	375	18	24	24	66	5	5.9	6	5.6	4				3	1	1			
23	84	192	192	468	12	24	24	60	7	8	8	7.6	4				1					
24	75	120	120	315	15	24	24	63	5	5	5	5	4				1	1				
25	80	120	120	320	16	24	24	64	5	5	5	5	4				5	5				
26														5	5	5	3	1				
27	90	99	75	264	18	24	24	66	5	4.1	3.1	4	4	0			1	1				
28	70	120	120	310	14	24	24	62	5	5	5	5	4				5	5	1			
29	80	120	120	320	16	24	24	64	5	5	5	5	4				3					
30	20				4			4	5			5	1	5	5	3	2					
31	25			25	5			5	5			5	1	4	4	4	3	1				
32	78	120	120	318	15	24	24	63	5.2	5	5	5.1	4				1	1				
33	75	110	120	305	15	22	24	61	5	5	5	5	4				3	1				
34	116	168	168	452	18	24	24	66	6.4	7	7	6.8	4				3	3	1			
35	48	96	96	240	12	24	24	60	4	4	4	4	4				3	1				
36	70	120	120	310	14	24	24	62	5	5	5	5	4	0	0	0	0	0	0	0	0	0
37	48	66	9	123	12	21	3	38	4	3.1	3	3.4	3			3	1	1				
38	72	96	138	306	18	24	24	66	4	4	5.7	4.5	4				1	1				
39	90	78	72	240	18	24	24	66	5	3.2	3	3.7	4				3	1	1			
40	20			20	5			5	4			4	1	5	5	5	1	1	1			
41	10			10	2			2	5			5	1	8	8	8	5	5	4	2		
42	10			10	2			2	5			5	1	8	8	8	8	5	4	2		
43	70	120	120	310	14	24	24	62	5	5	5	5	4				1	1				
44	60	99	96	255	12	24	24	60	5	4.1	4	4.3	4				1					
45	52	96	96	244	13	24	24	61	4	4	4	4	4				2	2	2	2		
46	70	120	120	310	14	24	24	62	5	5	5	5	4				3	1	1	1		
47	34	69	112	215	13	24	24	61	2.6	2.8	4.6	3.3	4				3	1				
48	85	120	120	305	17	24	24	65	5	5	5	5	4				4	2				
49														8	8	2	2	2	2			
50	90	120	120	330	18	24	24	66	5	5	5	5	4				3	1				
51	75	120	120	315	15	24	24	63	5	5	5	5	4				5	5				
52	48	117	120	285	12	24	24	60	4	4.9	5	4.6	4				1	1				
53	75	120	120	315	15	24	24	63	5	5	5	5	4				5	5	1			
54	20			20	4			4	5			5	1	8	8	8	3	1				

	CC	CD	CE	CF	CG	CH	CI	CJ	CK	CL	CM	CN	CO	CP	CQ	CR	CS	CT	CU
1	v471	v472	v473	v474	v475	v476	v477	v478	v479	v48	v491	v492	v493	v494	v495	v496	v501	v502	v503
2		3									1		1		1		3.42	1.04	1.97
3		2	2							MOROHINE D4	1		2	2	2	2	2.16		
4	0	0	0								1		1		1		2.23	2.21	1.18
5	3	3	3								1		1		1		2.91	1.04	1.61
6	0	0	0								1		1		1		2.9	1.23	1.97
7	3	3	3							INJ. VOVERAN 50MG TID	1		1		1		2.64	1.45	1.5
8	0	0	0								1		1		1		3.28	1.78	2.04
9	3	3								INJ. VOVERAN FOR BTA	1		1		1		3.76	2.42	3.17
10	3									1 DOSE INJ. VOVERAN	1		1		1		2.22	0.95	1.18
11	0	0	0								1		1		1		0.9	0.66	0.96
12	0	0								EPIDURAL LINE CAME O	1		1		1		2.19	1.61	1.85
13	0	0	0	0	0	0	0	0	0		1		1		2	3	3.56	1.82	
14		7	7							PT WAS GIVEN FEN PATC	1		1		1		1.71	1.02	0.83
15	0	0	0								1		1		1		1.38	0.81	1.04
16	6	6								EPI NOT WORKING. MOR	1		1		1		3.32	1.22	1.31
17	3	3								c.proxyvon	1		1		1		2.4	0.98	0.84
18	0	0	0	0	0						1		1		1		2.14	1.3	0.8
19	0	0	0	0	0						1		1		2	2	3.67	2.2	
20	0	0	0	0	0	0	0						1		1		2.89	2.35	2.9
21	0	0	0	0	0	0					1		1		1		2.53	1.98	0.89
22	0	3	3							1 DOSE EACH DAY	1		2	2	2	2	3.12		
23	3	0	0	0	0	0	0			INJ. VOVERAN 3 DOSES	1		2	2	2	2	3.39		
24	0	0	0	0							1		2	3	2	3	2.99		
25	0	0	0	0	0					INJ. MORPHINE 5MG S/C	1		1		1		2.1	1.39	1
26										EPIDURAL NOT PUT. MO	1		2	1	1		2.68		0.94
27	0	0	0	0							1		1		1		3.6	2.2	3.15
28	4									MORPHINE 5MG S/C 2 D	1		1		1		3.83	2.63	3.39
29	5	5	0	5						TOTAL 4 DOSES OF MOR	1		1		1		2.23	1.35	1.8
30	0	0								NON FUN EPI REMOVED	1		1		1		2.64	1.29	1.63
31	5									EPI NOT WORKING CAHN	1		1		1		1.98	0.58	1.18
32		0	5							PEA T.ULTRA CET ALON	1		1		1		3.53	2.49	1.63
33			5	5						MOR 5MG S/C Q4H FOR	1		1		1		3.86	1.72	1.64
34	0	3	3							INJ. VOV 50MG IV TID D	1		1		1		2.41	1.41	1.66
35	0	5								1 DOSE INJ. MORPHINE	1		1		1		1.94	0.7	0.76
36	0										1		2	2	1		2.03		1.5
37		3								bta Inj. Voveran 2 doses	1		1		1		1.94	1.01	1.05
38	0	0	0							EPI INCREASED TO 6ML/	1		2	3	2	3	3.45		
39	0	0	5							pod 3 inj. morphine 1 do	2	4	2	4	2	4			
40	0	0	0	0	0					MOR 2.5 MG S/CQ4H PO	1		1		1		1.79	1.25	0.86
41		0	0	0	0	0				FENTA MIDAZ INFUSION	1		2	1	2	1	1.91		
42			0	0	0	0	0	0		ICU EPI REMOVED FENT	1		2	1	1		3.28		1.85
43	0	0	0	0							1		1		1		1.49	1.61	1.59
44	0	0	0	0							2	4	2	4	2	4			
45	0	0	0								1		1		1		3.29	2.31	2.45
46	0	0	0								1		1		1		3.13	2.05	2.64
47	0	0	0	0							1		1		1		2.16	1.5	1.54
48	5	0	0	0	0					FENTANYLPATCH. MORP	1		1		1		3.52	2.5	1.89
49	3	3								dosifusion 48hrs. + inj. v	2	4	1		1			1.13	0.89
50	0	0	0	0							1		1		1		1.8	0.92	1.23
51	0	0	0								1		1		2	2	3.92	1.86	
52	0	0	0	0							1		1		1		3.67	3.77	3.69
53	0	0	0	0							1		1		1		3.39	2.15	2.88
54										FENTANYL INFUSION IN I	1		2	1	1		1.95		1.13

	CV	CW	CX	CY	CZ	DA	DB	DC	DD	DE	DF	DG	DH	DI	DJ	DK	DL	DM	DN
1	v511	v512	v513	v521	v522	v523	v53	v54	v541	v55	v56	v561	v562	v563	v57	v58	v59	v60	v61
2	3.05	0.79	1.69	89.2	75.4	85.6	2	1	2	2	2		2		2		28/08/2010	10	42
3	1.83			79.8			2	2	2	2	2				2		05/09/2010	7	62
4	2.21	0.9	1.07	99.2	95.7	90.7	2	1	2	2	2				2		18/09/2010	18	39
5	2.18	0.69	1.2	75	66.3	74.9	2	2	2	2	2				2		13/10/2010	20	57
6	2.32	0.91	1.6	79.9	74.6	81.2	2	1	2	2	2				2		04/11/2010	8	360
7	2.11	1.15	1.33	79.9	79.4	89	2	1	2	2	2				2		04/11/2010	11	69
8	2.66	1.45	1.64	81.3	81.7	80.5	1	1	2	1	1	NIL	2		2	ANASTOMO	24/11/2010	18	53
9	2.96	1.95	2.52	79.1	80.7	79.5	2	1	2	2	2				2	WOUND IN	12/12/2010	9	70
10	1.91	0.82	1.01	86.1	86	85.3	2	2	2	2	2				2	WOUND IN	08/01/2011	2.3	38
11	0.87	0.65	0.78	97	99.1	81.2	2	1	2	2	2		2		2	NO	15/01/2011	10	46
12	2.18	1.47	1.56	99.5	91.1	84	2	1	2	2	2		2		2	NO	16/01/2011	11	67
13	3.17	1.74		89	95.4		2	2	2	2	2				2		21/01/2011	11	36
14	1.52	0.92	0.64	88.7	89.9	77.1	1	2	1	1	1	NIL	1	NIL	2	WOUND IN	04/02/2011	16	192
15	1.18	0.63	0.82	85.6	78.1	79	2	1	2	2	2		2		2	WOUND IN	30/01/2011	17	72
16	2.8	0.93	1.19	84.3	76.5	91.2	2	3	2	2	2				2	NIL	04/02/2011	12	94
17	2.1	0.83	0.72	87.5	85	85.6	2	2	2	2	2				2		13/02/2011	8	69
18	1.68	1.04	0.55	78.7	79.8	69.5	2	1	2	2	2				2		12/03/2011	6	40
19	2.91	1.1		77.8	50.7		1	1	2	1	1	NIL	2		2	UTI, CENTR	05/04/2011	21	34
20	2.16	1.78	2.14	74.9	75.6	73.8	2	2	2	2	2				2		09/04/2011	18	50
21	2.29	1.72	0.53	90.4	86.6	60.1	2	1	2	2	2				2		11/04/2011	18	98
22	2.42			77.4			2	2	2	2	2				2		06/05/2011	10	94
23	2.68			79			1	2	2	2	2				2		15/05/2011	8	63
24	2.88			96.3			2	1	2	2	2				2		09/06/2011	16	73
25	1.7	1.11	0.96	80.8	79.9	79.9	2	3	2	2	2				2		02/07/2011	18	77
26	2.26		0.6	84.3		64.1	1	1	2	1	1	NIL	2		2	LINE SEPSIS	02/07/2011	18	55
27	2.9	1.53	2.58	88	69.6	82	2	3	2	2	2				2		13/07/2011	14	50
28	2.95	2.07	2.61	77.1	78.6	77	2	1	2	2	2		2		2		05/08/2011	10	90
29	1.73	1.13	1.36	77.5	78.7	78.7	2	1	2	2	2				2				
30	2.38	1.19	1.63	95.3	99	82.4	2	2	2	2	2				2		24/08/2011	16	48
31	1.98	0.56	1.04	99	69.1	88.1	1	2	2	2	2				2		11/09/2011	18	75
32	2.75	2	1.17	77.3	76.1	72.2	2	3	2	2	2				2		11/09/2011	7	41
33	3.26	1.51	1.36	84.4	88.1	82.6	2	1	2	2	2		2		2		17/09/2011	9	42
34	1.9	1.07	1.24	78.9	80.9	83.5	2	3	2	2	2		2		2		22/09/2011	11	71
35	1.51	0.61	0.55	83.4	71.4	72.2	2	2	2	2	2		2		2		24/09/2011	18	48
36	1.67		1.16	91.9		69.1	2	1	2	2	2		2		2		26/09/2011	15	72
37	1.75	0.94	0.91	90.1	92.9	86	2	2	2	2	2				2		12/10/2011	6	38
38	2.91			84.3			2	1	2	2	2				2		23/11/2011	18	55
39							2	1	2	2	2		2		2		10/12/2011	18	51
40	1.62	0.91	0.66	90.6	90.5	76.4	2	1	2	2	2				2		30/01/2012	9	67
41	1.62			84			2	1	1	1	1	PATCH	2		1				
42	2.79		1.36	85.6		74.7	2	2	2	2	1	NIL			2		26/02/2012	18	77
43	1.17	1.25	1.29	78.7	77.3	81.4	2	1	2	2	2		2		2		03/03/2012	10	43
44							2	1	2	2	2		2		2		14/03/2012	16	47
45	2.67	1.34	1.65	83.5	58.1	67.5	2	1	2	2	2		2		2		19/03/2012	9	64
46	2.84	1.8	2.19	95.3	99.8	98.7	2	1	2	2	2		2		2		05/04/2012	9	66
47	1.79	1.32	1.26	82.9	89	78.1	2	1	2	2	2		2		2		06/04/2012	19	101
48	2.89	2.03	1.48	82.4	83.8	78.9	2	2	2	2	2				2		22/04/2012	6	89
49		1.08	0.86		89.7	81.5	1	2	2	2	2		2		2		28/04/2012	9	112
50	1.66	0.9	1.09	83.3	96.7	90.9	2	3	2	2	2		2		2		27/04/2012	21	57
51	3.04	1.42		76.7	76.4		2	2	2	2	2		2		2		12/05/2012		
52	2.83	2.93	2.97	76.3	79.1	80.4	2	2	2	2	2		2		2		30/05/2012	10	42
53	2.37	1.39	2.37	69.8	64.9	82.4	2	1	1	1	2		2		1	CLINICAL	06/07/2012	21	54
54	1.62		0.79	82.7		69.5	2	1	2	2	2		2		2		07/07/2012	22	77

	DO	DP	DQ	DR	DS	DT	DU	DV	DW	DX	DY	DZ	EA	EB
1	v62	v63	v64	v65	v66	v67	v68	v69	v70	v71	v72	v73	v74	v75
2	30/08/2010	12	92	2		30/08/2010	5	2			2			1
3	05/09/2010	9	64	2		05/09/2010	4	2			2			2
4	20/09/2010	9	91	2		20/09/2010	5	2			2			2
5	14/10/2010	16	77	2		15/10/2010	5	2			2			1
6	05/11/2010	5	384	1	4	05/11/2010	16	1	5	ANAS	2			1
7	04/11/2010	19.3	77	2		06/11/2010	6	1	12	ANAS	1	12	ANASTOMOTIC	1
8	25/11/2010	21	80	2		26/11/2010	5	1	8	ANAS	1	8	FEVER ANASTO	1
9	13/12/2010	8	93	1	4	13/12/2010	5	2			2			2
10	08/01/2011	3.3	39	1	4	09/01/2011	14	2		STAY	2			2
11	16/01/2011	16.3	77	2		16/01/2011	4	2			2			2
12	17/01/2011	9	89	2		17/01/2011	5	2			2			2
13	22/01/2011	14	51	2		25/01/2011	6	2			2			1
14	05/02/2011	16	216	1	5	09/02/2011	14			PUL E	2			2
15	30/01/2011	22	77	1	4	01/02/2011	5	2			2			2
16	04/02/2011	22	104	2		05/02/2011	6	2				2		1
17	14/02/2011	7	92	2		15/02/2011	6	2			2			1
18	13/03/2011	16	74	2		17/03/2011	8	2			2			1
19	06/04/2011	10	47	2		21/04/2011	17	2		SEPSIS PROLONGED HOSPITAL STAY				2
20	10/04/2011	19	75	2		11/04/2011	5	2			2			1
21	12/04/2011	8	112	2		12/04/2011	6	2			2			2
22	07/05/2011	12	120	1	3	07/05/2011	6	2			2			1
23	15/05/2011	18	73	2		16/05/2011	6	2			2			1
24	10/06/2011	14	95	2		10/06/2011	5	2			2			1
25	05/07/2011	10	93	2		05/07/2011	6	2			2			2
26	03/07/2011	14	76	2		14/07/2011	15	1	5	? ANA	2			2
27	15/07/2011	4	88	2		15/07/2011	5	2			2			2
28	06/08/2011	19	124	2		06/08/2011	6	2			2			2
29				2		26/08/2011	5	2		HAD I	2			1
30	26/08/2011	9	89	1	6	26/08/2011	5	2			2		STAY PROLONG	2
31	13/09/2011	8	114	2		13/09/2011	6	2			2			1
32	11/09/2011	9	43	2		15/09/2011	7	2		LOOSE STOOLS REQUIRED IV FLUIDS				1
33	19/09/2011	9	90	1	3	19/09/2012	5	2			2			2
34	24/09/2011	8	116	2		24/09/2011	6	2			2			1
35	25/09/2011	18	72	2		26/09/2011	5	2			2			1
36	26/09/2011	22	79	2		27/09/2011	5	2			1	8	Uro sepsis	2
37	12/10/2011	11	43	2		13/10/2011	4	2			1	9	fever. antibioti	2
38	24/11/2011	16	77	2		24/11/2011	4	2			2			2
39	12/12/2011	8	89	2		12/12/2011	5	2			2			2
40	30/01/2012	10	68	2		03/02/1012	8	2		PARALYTIC ILEUS WITH VOMITING				1
41	25/02/2012			2		27/02/2012	8	2		MI ICU	2			1
42	27/02/2012	22	105	2		28/02/2012	6	2		ICU, H	2			1
43	04/03/2012	2	59	2		04/03/2012	4	2		STOM	2			2
44	15/03/2012	10	65	2		15/03/2012	4	2			2			2
45	20/03/2012	14	93	1	4	20/03/2012	5	2		ACTU	2			2
46	06/04/2012	10	89	1	4	16/04/2012	15	1	8	ANAS	2			2
47	07/04/2012	10	116	2		07/04/2012	6	2			2			1
48	22/04/2012	22	105	2		23/04/2012	6	2			2			1
49	29/04/2012	13	140	1	4	29/04/2012	7	2		wpw s	2			2
50	28/04/2012	8	68	1	4	28/04/2012	4	2			2			1
51	12/05/2012			2		14/05/2012	12	1	5	ANAS	2			2
52	30/05/2012	18	50	2		30/05/2012	3	2			2			2
53	08/07/2012	18	96	2		08/07/2012	5	2			2			2
54	08/07/2012	9	86	1	4	11/07/2012	8	2		LOOSE	2			1

CHRISTIAN MEDICAL COLLEGE
VELLORE - 632 004. INDIA
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Secretary, Ethics Committee, IRB,
Additional Vice Principal (Research)

July 27, 2010

Dr. Titus D.K.
Department of Surgery
Christian Medical College
Vellore 632 004

Sub: **FLUID Research grant project NEW PROPOSAL:**
Midline Vs Transverse incision for right, left and segmental colectomy.
Dr. Titus D.K, Surgery, Dr. Benjamin Perakath, Dr. Sukria Nayak, Dr. Mark Ranjan Jesudasan, Surgery, Dr. Sarah Ninan ,Anaesthesia, Dr. Christopher D.J, Pulmonary Medicine, Dr. Rohin Mittal, Surgery.

Ref: IRB Min. No. 7220 dated 21.07.2010

Dear Dr. Titus,

The Institutional Review Board (Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Midline Vs Transverse incision for right, left and segmental colectomy" on July 21, 2010.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Informed Consent Form and Information Sheet (English, Tamil, Hindi and Bengali)
3. Cvs of Drs. Benjamin Perakath, DJ Christopher, Sukria Nayak, Mark Ranjan Jesudasan, Rohin Mittal.
4. A CD containing document 1 -3

The following Ethics Committee members were present at the meeting held on July 21, 2010 at 10:00 am in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Other Affiliatio
Dr. George Thomas	MBBS, D.Ortho	Chairperson (IRB) & Orthopaedic Surgeon, St. Isabel Hospital, Chennai & Editor, Indian Journal of Medical Ethics	Non-CMC Staff.

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Chairman, Research Committee,&
Principal

Dr. Gagandeep kang, MD, PhD, FRCPath
Deputy Chairperson,
Secretary, Ethics Committee, IRB,
Additional Vice Principal (Research)

Dr. Shuba Kumar	MA, MSc, Ph.D.	Dy. Chairperson (IRB) & Social Scientist, SAMRATH, Chennai.	Non-CMC Staff.
Dr. George Mathew	MBBS, MS, MD	Principal, C.M.C.	
Dr. Prathap Tharyan	MD, MRCPsych.	Associate Director, Professor of Psychiatry, CMC	
Mrs. Mary Johnson (on behalf of Mrs. Sundari Edwin)	M.Sc. (Nursing)	Nursing Superintendent, CMC.	
Rev. Malhia Joshua	MA, MEd, MTh, PhD	Chaplain, CMC	
Mr. Harikrishnan	BL.	Lawyer	Non-CMC Staff.
Dr. Sujith Chandy	MBBS, MD	Professor, Pharmacology Dept. CMC.	
Mrs. S. Pattabiraman	BSc, DSSA	Social Worker, Vellore	Non-CMC Staff
Dr. Jayaprakash Muliyil	BSC, MBBS, MD, M DrPH(Epid), DMHC	Academic Officer, CMC	
Dr. Gagandeep Kang	MD, PhD, FRCPath.	Secretary IRB (EC)& Dy. Chairperson (IRB). Professor of Microbiology & Addl. Vice Principal (Research), CMC.	

We approve the project to be conducted in its presented form.

The Institutional Ethics Committee / Independent Ethics Committee expects to be informed about the progress of the project, any SAE occurring in the course of the project, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

A sum of Rs.73, 944/- (Rupees Seventy three thousand nine hundred and forty four only) is sanctioned for 2 years out of which a maximum of Rs. 1,500/- can be spent for stationery, printing, Xeroxing and computer charges (if computers used are within the institution).

Yours sincerely,

Gagandeep Kang, MD, PhD, FRCPath
Secretary, IRB

Secretary
Institutional Review Board
(Ethics Committee)
Christian Medical College
Vellore - 632 002, Tamil Nadu, India

TEL : 0416 - 2284294, 2284202 FAX : 0416 - 2262788 / 2284481 e-mail : research@cmcvellore.ac.in